FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

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
02/2021	Dossier sent for evaluation
04/2022	zRMS evaluation of dRR
July 2022	Final version prepared by zRMS after Commenting period
December 2022	zRMS updated finalised evaluation

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zRMS comments:
The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

The application from Syngenta is for the first authorisation for A18385B under Article 33 of Regulation (EC) 1107/2009 in Poland. A18385B is a water dispersible granule (WG) containing 40g/kg prosulfuron, 100g/kg nicosulfuron, and 400g/kg dicamba for use as an herbicide in maize.

No equivalence assessment is required.

This application follows the data requirements for the active substances laid down in Regulation (EU) No. 544/2011[1] and the data requirements for the plant protection product laid down in Regulation (EU) No. 284/2013.

The owner of the data for nicosulfuron is Cheminova A/S with the exception of certain technical substance equivalence data which is jointly owned by Syngenta and Cheminova. The right to refer Regulatory Authorities to these data has been granted to Syngenta by Cheminova A/S (letter of access provided).

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name, authorization no. (if relevant)	**cMS, MS' product name, authorization no. (if applicable)**
Northern zone	Not applicable	Not applicable
Central zone	Poland, SPANDIS	Not applicable
Southern zone	Not applicable	Not applicable
Inter-zonal	Not applicable	Not applicable

0.1.3 Regulatory history of the active(s)

0.1.3.1 Prosulfuron

Table 0.1-2: Summary of regulatory history of CAS No: 94125-34-5

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Regulation (EU) 2017/375
RMS	France
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.05.2017

[1] Old AS data requirements and new PPP data requirements continue to apply (in accordance with Reg. (EU) No 284/2013 as amended by Reg. (EU) No 2015/1475) following SANTE/11509/2013 – rev. 5.2 (09 October 2015).

Status	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.12.2002
Date of final Commission (re-registration) deadline (Step 2)	31.12.2003
Current expiration of approval	30.04.2024
Low risk substance or Candidate for Substitution?	CfS

The Final Addendum to the Renewal Assessment Report (France[2], September 2014) and the Review Report on Prosulfuron (SANTE/10682/2015 Rev. 3, 24 January 2017) are considered to provide the relevant information on the evaluation or a reference to where such information can be found. In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EU) 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the re-evaluation process. This endpoints are listed in the conclusion of the EFSA from 11 March 2015 (EFSA Journal 2014;12(9):3815) and from 11 June 2020 (EFSA Journal 2020;18(7):6181). Those versions replaces the earlier version published on 02 September 2014.

On the basis of the representative uses supported by available data (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

- Use shall be limited to a maximum total dose of 20g active substance per hectare every third year on the same field.

Member States must pay particular attention to:

- The protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.
- The risk to non-target terrestrial and aquatic plants.

Conditions of use shall include risk mitigation measures, where appropriate.

Table 0.1-3: Information on minimum purity of Prosulfuron

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, ** **
950 g/kg	N/A; min. purity of active substance used in the product is 950 g/kg

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

[2] French Ministry of Agriculture, Agrifood, and Forestry

Endpoint	Prosulfuron	
	EU agreed endpoint from EFSA Journal 2014;12(9):3815	**Endpoint used***
DT_{50} in soil for PEC_{gw} and PEC_{sw} modelling [d]	62.1 (normalised lab geometric mean, n = 10)	Tier 1: 62.1 (normalised lab geometric mean, n = 10) Tier 2: ~~20.8~~[a] 18.7 (normalised field geometric mean, n = 6)
K_{foc} for PEC_{gw} calculation [mL/g]	14.2 (arithmetic mean, n = 8)	Tier 1, Tier 2a: 14.2 (arithmetic mean, n = 8) Tier 2b, Tier 2c: 11.7 (geometric mean, n = 8)[b]

* Since EU approval new studies on the active substance have been performed

[a] ~~The value of 20.8 days was taken from the original issued report by Hardy & Jastrzebski, 2015 (Syngenta File No CGA152005_10792) and is used in the modelling. In the meantime the report was re-issued with a corrected geometric mean value of 21.2 days (erroneous core diameters were given in the original data for the Spanish trial). Despite this shortcoming Syngenta considers the value of 20.8 days appropriate for use in risk assessment, because it is consistent with the calculated dissipation rates from the 6 trials (range from 11.9 – 53.7 days~~ In accordance with EFSA, 2020

[b] Geometric mean values were calculated and considered in agreement with EFSA (2014)[3]

Endpoint	Metabolite SYN547308	
	EU agreed endpoint from EFSA Journal 2014;12(9):3815	**Endpoint used***
DT_{50} in soil [d]	-	67.1 (normalised lab geometric mean, n = 3)
K_{foc} for PEC_{gw} calculation [mL/g]	-	Tier 1, Tier 2a: ~~131.2 (arithmetic mean, n = 5)~~ Tier 2b, Tier 2c: 89.5 ~~113.1~~ (geometric mean, n = 8)

* ~~Since EU approval new studies have been performed~~ In accordance with EFSA Journal 2020;18(7):6181

Endpoint	Metabolite CGA349707	
	EU agreed endpoint from EFSA Journal 2014;12(8):3801	**Endpoint used***
Earthworm, chronic	-	NOEC = 100 mg/kg dw
Folsomia candida, chronic	-	NOEC = 100 mg/kg dw
N- and C- mineralisation	-	NOEC = 0.135 mg/kg dw soil

* Since EU approval new studies have been performed

[3] EFSA (2014): EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain $DegT_{50}$ values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014; 12(5):3662.

Endpoint	Metabolite CGA159902	
	EU agreed endpoint from EFSA Journal 2014;12(8):3801	**Endpoint used***
Earthworm, chronic	-	NOEC = 17.1 mg/kg dw
Folsomia candida, chronic	-	NOEC = 30.9 mg/kg dw

* Since EU approval new studies have been performed

Endpoint	Metabolite SYN542604	
	EU agreed endpoint from EFSA Journal 2014;12(8):3801	**Endpoint used***
Earthworm, chronic	-	NOEC = 100 mg/kg dw
Folsomia candida, chronic	-	NOEC = 100 mg/kg dw

* Since EU approval new studies have been performed

Endpoint	Metabolite CGA325025	
	EU agreed endpoint from EFSA Journal 2014;12(8):3801	**Endpoint used***
Earthworm, chronic	-	NOEC = 100 mg/kg dw
Folsomia candida, chronic	-	NOEC = 100 mg/kg dw

* Since EU approval new studies have been performed

Endpoint	Metabolite CGA300406	
	EU agreed endpoint from EFSA Journal 2014;12(8):3801	**Endpoint used***
Earthworm, chronic	-	NOEC = 95 mg/kg dw
Folsomia candida, chronic	-	NOEC = 1000 mg/kg dw

* Since EU approval new studies have been performed

0.1.3.2 Nicosulfuron

Table 0.1-4: Summary of regulatory history of CAS No: 111991-09-4

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2008/40/EC of 28 March 2008 Implementing Regulation Reg. (EU) 2020/1511
RMS	LV
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2009

Status	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.06.2009
Date of final Commission (re-registration) deadline (Step 2)	31.12.2012
Current expiration of approval	31.12.2021
Low risk substance or Candidate for Substitution?	CfS

The SANCO report for nicosulfuron (SANCO/3780/07 – rev. 1 – 22/01/2008) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 29 November 2007 (DOI: 10.2903/j.efsa.2008.120r)

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the potential aquatic exposure to metabolite DUDN for acidic water bodies
- the potential for groundwater contamination
- risk mitigation measures such as a no-spray buffer zone to mitigate the risk to aquatic organisms
- risk mitigation measures to protect non-target plants in the off-field area

Table 0.1-5: Information on minimum purity of nicosulfuron

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
910 g/kg	N/A; min. purity of active substance used in the product is 910 g/kg

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	**Nicosulfuron**	
	EU agreed endpoint from EFSA scientific report	**Endpoint used***
	-	N/A

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data).

0.1.3.3 Dicamba

Table 0.1-6: Summary of regulatory history of CAS No: 1918-00-9

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 Commision Implementing Regulaiton (EU) No 2020/1511
RMS	DK
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.06.2009
Date of final Commission (re-registration) deadline (Step 2)	31.12.2013
Current expiration of approval	31.12.2021
Low risk substance or Candidate for Substitution?	N/A

The SANCO report for dicamba (SANCO/829/08 – rev.1 – 07/03/2008 and SANCO/829/08 – final rev. 2 12/07/2016) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 14 January 2011 (EFSA Journal 2011;9(1):1965).

Table 0.1-7: Information on minimum purity of dicamba

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
850 g/kg	N/A; min. purity of active substance used in the product is 850 g/kg

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	**Dicamba**	
	EU agreed endpoint from EFSA scientific report	**Endpoint used***
	-	N/A

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data).

0.1.4 Regulatory history of the product

The following table provides corresponding information of product codes, product names and authorizations in different EU Member States.

Table 0.1-8: Summary of regulatory history of the product A18385B

Product code	Product name(s)	MS	Authorization No.	Date of initial registration	Date of the last re-registration
A18385B	SPANDIS	AT	Ongoing	Ongoing	N/A
A18385B	SPANDIS DINIRO	BE	Ongoing	Ongoing	N/A
A18385B	SPANDIS	CZ	5234-0	11.05.2017	N/A
A18385B	SPANDIS	HU	Ongoing	Ongoing	N/A
A18385B	SPANDIS DINIRO	NL	15345 N 15393 N	12.05.2017	N/A
A18385B	SPANDIS	RO	Ongoing	Ongoing	N/A
A18385B	SPANDIS	SI	U34330-241/14/5	01.04.2017	N/A
A18385B	SPANDIS	SK	16-11-1845	14.02.2017	N/A
A18385B	SPANDIS	UK	Ongoing	Ongoing	N/A
A18385B	SPANDIS	BG	Ongoing	Ongoing	N/A
A18385B	SPANDIS	ES	Ongoing	Ongoing	N/A
A18385B	GRANARY	FR	Ongoing	Ongoing	N/A
A18385B	SPANDIS	GR	Ongoing	Ongoing	N/A
A18385B	SPANDIS	HR	Ongoing	Ongoing	N/A
A18385B	DINIRO	IT	Ongoing	Ongoing	N/A
A18385B	SPANDIS	MT	2017-04-10 P01 (SZ)	10.04.2017	N/A
A18385B	SPANDIS	PT	Ongoing	Ongoing	N/A

A18385B/SPANDIS was not the representative formulation during the renewal of approval (AIR2) of the active substance prosulfuron under regulation (EC) No 1107/2009. The product has been evaluated according to the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the Uniform Principles laid down in Regulation (EU) No 546/2011.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information
~~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.~~

Section 3. Efficacy
The evaluation of the application of Spandis 54 WG resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical methods
The analytical methods used accepted.

Section 6: Mammalian Toxicology
Based on study results in combination with the calculation method, Spandis 54 WG is classified as Eye Irrit. 2, H319 (Causes serious eye irritation).
The results of exposure assessment indicate that Spandis 54 WG is safe for operator, worker as well as bystander and resident (both adult and child). Due to the classification of the product it is recommended to wear eye protection/face protection when handling the product.

Section 7. Metabolism and Residues
The residue data provided are sufficient for granting the requested authorization for Spandis 54 WG. The proposed use in maize can be accepted. The relevant MRLs are not expected to be exceeded. The use of the product does not lead to unacceptable risk for consumers when applied according to the recommendations. Furthermore, in the context of the authorization request the required analytical residue methods are available and considered adequate.

Section 8. Environmental Fate
In accordance with intended use in maize, an exposure assessment for the formulation SAE053H/01 was submitted and sufficient. The application in maize is acceptable if the formulation is used every third year.

Section 9. Ecotoxicology
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of Spandis 54 WG as herbicide on maize poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from Spandis 54 WG applications are required for: aquatic organisms, non-target terrestrial plants.

Section 10. Assessment of the relevance of metabolites in groundwater
The prosulfuron and nicosulfuron metabolites can be considered to be non-relevant according to the criteria set in the guidance document SANCO/221/2000-rev.10. No dicamba metabolites with PEC > 0.1 µg/L were identified, therefore further assessment of the potential metabolites relevance is not required.

Uses to be considered safe on the basis of EU methodology:

1, 2

Uses to be considered non-safe on the basis of EU methodology:

none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

none

Appendix 1 ALL intended uses

PPP (product name/code):	Spandis / A18385B	Formulation type[a,b]:	Water dispersible granules (WG)
Active substance 1:	Prosulfuron	Conc. of as 1[c]:	40 g/kg
Active substance 2:	Nicosulfuron	Conc. of as 2[c]:	100 g/kg
Active substance 3:	Dicamba	Conc. of as 3[c]:	400 g/kg
Safener:	N/A	Conc. of safener[c]:	N/A
Synergist:	N/A	Conc. of synergist[c]:	N/A
Applicant:	Syngenta	Professional use:	
Zone(s)[d]:	Central	Non professional use:	
Verified by MS:	yes/~~no~~		
Field of use:	Herbicide		

1	2	3	4	5	6	7	8	9	10	11	11	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, 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 [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg A18385B/ ha a) max. rate per appl. b) max. total rate per crop/season	g prosulfuron/ha a) max. rate per appl. b) max. total rate per crop/season	g nicosulfuron/ha a) max. rate per appl. b) max. total rate per crop/season	g dicamba/ ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)															
1	PL	Maize	F	Annual/ perennial broad leave weeds and grasses	Foliar spray	BBCH 12-18	1 (1 appl. every 3rd year)	N/A	a) 0.5 b) 0.5	a) 20 b) 20	a) 50 b) 50	a) 200 b) 200	~~200~~ 150-400	n.s.	tank-mixed oil-based adjuvant needed ~~(e.g Adigor 440 EC @~~ 1.0-1.5L/ha~~)~~

~~1~~ 2	PL	Maize	F	Annual/ perennial broad leave weeds and grasses	Foliar spray	BBCH 12-18	1 (1 appl. every 3rd year)	N/A	a) 0.4 b) 0.4	a) 16 b) 16	a) 40 b) 40	a) 160 b) 160	~~200~~ 150-400	n.s.	proportional mitigation; tank-mixed oil-based adjuvant needed ~~(e.g. Adigor 440 EC @~~ 1.0-1.5L/ha~~)~~

Remarks table heading:

(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.

Remarks columns:

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 equipment (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
n.s.: not specified; the PHI is covered by the time remaining between application and harvest
14 Remarks may include: Extent of use/economic importance/restrictions