

# **FINAL REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**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**

## **NATIONAL ASSESSMENT**

**Poland**

**(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
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September 2022	zRMS updated finalised evaluation
December 2022	zRMS updated finalised evaluation

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# **PART A**

## **RISK MANAGEMENT**

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

#### **Summary of the additional information submitted for the national evaluation of A18385B:**

No additional information is submitted for the national evaluation of A18385B. The relevant data and assessments for the evaluation of A18385B in Poland are part of the core dossier.

#### **1.1 Application background**

This application was submitted by Syngenta. Poland is the zRMS for the evaluation.

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

To obtain authorization the product A18385B, must (where appropriate) meet the conditions of a.s. EU inclusion and be supported by a dossier satisfying the requirements of Commission Regulation (EU) No. 284/2013 and the associated Annex, which repeals Commission Regulation (EU) No 545/2011 which under Regulation (EC) 1107/2009, replaced the requirements of Annex III to Directive 91/414/EEC.

The application was submitted in order to allow the authorization of this product/use in the Member State Poland in accordance with the above.

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

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).

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

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

This is new plant protection product, which is intended to be authorized in Member State for the first time. There is no repetition of studies involving vertebrates. Animal studies were only performed where there were no data available to address an endpoint, no extrapolation to existing data possible or the available data were not done according to modern guidelines. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.

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

This is new plant protection product, and there is no EU derogation allowing for these data points to be addressed by extrapolating from existing data; and there have been changes to active substance endpoints and test, study and assessment guidelines; therefore where necessary in order to obtain approval new tests and study reports are provided.

#### **1.4 Data protection claims**

Where protection for data is being claimed for information supporting registration of A18385B, in accordance with Article 59 of Regulation (EC) No. 1107/2009.

### **2 Details of the authorization decision**

## 2.1 Product identity

Product code	A18385B
Product name in MS	SPANDIS
Authorization number	n/a
Function	Herbicide
Applicant	Syngenta Polska Sp. z o.o.
Active substance(s) (incl. content)	Dicamba, 400 g/kg Nicosulfuron, 100 g/kg Prosulfuron, 40 g/kg
Formulation type	Water dispersible granule [WG]
Packaging	50 g, 100 g, 250 g, and 0.5 kg, 1 kg, 5 kg and 10 kg HDPE canisters (Registrant: Syngenta. Marketed by: Syngenta.)  500 g, and 1 kg, 1.8 kg, 2 kg, 2.4 kg, 3 kg, 4.8 kg, 5 kg, 9.6 kg and 10 kg HDPE/ co-ex HDPE/PA / f-HDPE/ PET canisters (Registrant: Syngenta. Marketed by: Cheminova)
Coformulants of concern for national authorizations	There are no coformulants of concern in A18385B
Restrictions related to identity	Technical prosulfuron should contain less than 10g/kg of 2-(3,3,3-trifluoro- propyl)-benzene sulphonamide
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

## 2.2 Conclusion

Section B7: The evaluation of the application for SPANDIS 54 WG (A18385B) resulted in the decision to grant the authorization (please, see 2.6 – the accepted GAP).

## 2.3 Substances of concern for national monitoring

Not applicable.



## 2.4 Classification and labelling

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

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

Hazard class(es), categories:	Eye Irritation Category 2 Acute aquatic toxicity Category 1 Chronic aquatic toxicity Category 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	  <b>GHS07 GHS09</b>
Signal word:	<b>Warning</b>
Hazard statement(s):	<b>H319 Causes serious eye irritation</b> <b>H410 Very toxic to aquatic life with long lasting effects</b>

Precautionary statement(s):	<b>P264</b> <b>P280</b> <b>P305 + P351 + P338</b>  <b>P337 + P313</b>  <b>P391</b> <b>P501</b>	<b>Wash skin thoroughly after handling.</b> <b>Wear eye protection/face protection</b> <b>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</b> <b>If eye irritation persists: Get medical advice/attention</b> <b>Collect Spillage</b> <b>Dispose of contents/ container to an approved waste disposal plant</b>
Additional labelling phrases:	<b>EUH401</b>	<b>To avoid risks to man and the environment, comply with the instructions for use</b>

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

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination <i>via</i> drains from farmyards and roads).
SPe3	To protect aquatic organisms respect an unsprayed, vegetated buffer zone of 5 m to surface water bodies. To protect non-target plants respect an unsprayed buffer zone of 5m to non-agricultural land or 1 m associated with a 90% drift reducing techniques (500 g product/ha) or or 1 m associated with a 75% drift reducing techniques (400 g product/ha).

## 2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

Refer to national product label
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## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

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

Operator protection:	
None	Due to the classification of the product - Wear eye protection/face protection when handling the product.
Worker protection:	
None	N/A
Integrated pest management (IPM)/sustainable use:	
respective code if available : N/A	On the basis of all available information as documented in Part B-Section 3, the overall risk of resistance can be considered low.
Environmental protection	
	To protect aquatic organisms: Respect 5 m no-spray buffer zone and a 5 m vegetated buffer strip.  To protect non-target plants:

	<u>1 x 400 g A18385B/ha:</u> <ul style="list-style-type: none"> <li>• 75% drift reduction or</li> <li>• 5 m buffer</li> </ul> <u>1 x 500 g A18385B/ha:</u> <ul style="list-style-type: none"> <li>• 90% drift reduction mitigation or</li> <li>• 5m buffer</li> </ul>
Other specific restrictions	
respective code if available : N/A	None

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

Integrated pest management (IPM)/sustainable use:	
respective code if available : N/A	None

## 2.5.2 Specific restrictions linked to the intended uses

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

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
respective code if available : N/A	None	-
Environmental protection:		Relevant for use no.
respective code if available : N/A	None	-



## 2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Spandis / A18385B  
Active substance 1: Prosulfuron  
Active substance 2: Nicosulfuron  
Active substance 3: Dicamba  
Safener: N/A  
Synergist: N/A  
Applicant: Syngenta  
Zone(s)<sup>(d)</sup>: Central  
Verified by MS: yes  
Field of use: Herbicide

Formulation type<sup>(a,b)</sup>: Water dispersible granules (WG)  
Conc. of as 1<sup>(c)</sup>: 40 g/kg  
Conc. of as 2<sup>(c)</sup>: 100 g/kg  
Conc. of as 3<sup>(c)</sup>: 400 g/kg  
Conc. of safener<sup>(c)</sup>: N/A  
Conc. of synergist<sup>(c)</sup>: N/A  
Professional use: ☒  
Non professional use: ☐

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

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		
							year)								needed Adigor 440 EC@ 1.0- 1.5 L/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
- 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.
  - (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.
  - 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

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

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

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**

All physico-chemical endpoints were measured using A18385B. Thus, no bridging to other formulations is required.

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

A18385B is a post emergence herbicide for the control of annual and some perennial dicot weeds as well as for grasses in corn (maize). A18385B is a water dispersible granule (WG) containing 100 g/kg of nicosulfuron, 40 g/kg of prosulfuron and 400 g/kg of dicamba.

A18385B (synonym CHA 7980) is an herbicide based on the well-known and proven active ingredients nicosulfuron, prosulfuron and dicamba. Up to now A18385B is authorised in most of European countries. A18385B was jointly developed and tested by Syngenta and Cheminova A/S. The Syngenta development code is A18385B and the Cheminova A/S development code CHA 7980. A18385B and CHA 7980 are the two company's different development codes for the same product. For ease of reading the code used throughout the Biological Assessment Dossier is A18385B.

The single active ingredients nicosulfuron, prosulfuron and dicamba are well-known herbicides, widely used throughout the world for many years. In Europe they are authorised in almost all countries where maize is grown under a number of different trade names, either as straight single a.i. based products or in combination with other maize selective active ingredients.

This dossier fully supports the label claims for A18385B in controlling a wide range of grass and broadleaved weeds commonly found in maize, whilst offering sufficient crop safety.

### 3.3 Efficacy data

In maize, the proposed maximum rate of A18385B is 0.5 l/ha with a maximum of one application per season, which will deliver 50 g nicosulfuron, 20 g prosulfuron and 200 g dicamba per hectare. In order to support the proposed use of A18385B data is presented from trials conducted over 4 seasons 2012-2015 in a range of European countries in the Maritime (Germany and Czech Republic) and North-East (Poland) EPPO zone. The combination of nicosulfuron, prosulfuron and dicamba in A18385B will provide broad spectrum foliar control against grass and broadleaved weeds with good crop safety.

#### Minimum effective dose of A18385B

In order to prove and to support the requested dose rates of A18385B applied post-emergent for the control of grasses and broad-leaved weeds in maize (0.5 kg/ha for the North-East), the assessment results of 28 efficacy trials performed in 2012 and 2013 in Central and Northern Europe are submitted in this dossier.

The dose response effects are demonstrated by the activity of A18385B against a selection of important annual and perennial grass and broad-leaved weed species being of relevance in maize in Europe.

Based on the data presented from the North-East EPPO zone it is demonstrated that some weed species, such as the *Chenopodium* species or *Amaranthus retroflexus*, are controlled by A18385B applied at 0.4 kg/ha. However, to consistently and adequately control all target weed species the intended dose rate of 0.5 kg/ha is required. Same for the efficacy against *Echinochloa crus-galli* which showed not significant difference between the two rates. A18385B applied at 0.5 kg/ha provides the best overall control on a wide range of annual broad-leaved weeds and grasses in maize in the North-East EPPO zone.

#### Efficacy of A18385B

A total of 35 trials were conducted according to the relevant EPPO guidelines: PP1/050 "Weeds in Maize", PP1/152 "Design and Analysis of Efficacy Evaluation Trials", PP1/181 "Conduct and Reporting of Efficacy Evaluation Trials".

Trials presented in this dossier for the European Central Regulatory zone have been carried out in EPPO zone Maritime (21) and EPPO zone North-East (12), between 2012 and 2015.

The results of 33 field trials concluded for the intended use '*Grasses and broad-leaved weeds in maize*' of A18385B (+ adjuvant) applied post-emergence at the dose rate of 0.5 kg/ha in the North-East EPPO zone:

- A18385B applied at 0.5 kg/ha in the North-East and Maritime EPPO zones provides good to very good control of almost all key weeds in European maize cultivation.
- Compared to the reference products A18385B applied at 0.5 kg/ha in the North-East and supporting Maritime zones achieves comparable levels of grass control and comparable to superior control of broad-leaved weeds.
- The spectrum of weeds controlled by A18385B is wider than the standard products.
- The trial results obtained are considered valid for Poland. Thus, the trials conducted in an adjacent EPPO climatic zone in Germany and Czech Republic can be seen as supportive evidence towards the weed spectrum of A18385B.

Based on the efficacy data results it can be concluded that A18385B can be authorised for control of grass and broadleaved weeds in maize following these recommendations:

A18385B is recommended for use in the North-East EPPO zone at 0.5 kg/ha dose rate for control of ALOMY, ECHCG, SETVI, AGRRE and dicot weeds in maize. The product is recommended as post emergence treatment to crop (BBCH 12-18) and weeds in spring. The maximum number of applications per crop is one.

Weed control spectrum of A18385B (0.5 kg/ha) + adjuvant that can be claimed on the label in maize in Poland:

Scientific name	English common name	EPPO code
<b>susceptible <math>\geq 85\%</math></b>		
<i>Echinochloa crus-galli</i>	cockspur	ECHCG
<i>Amaranthus retroflexus</i>	common amaranth	AMARE
<i>Capsella bursa-pastoris</i>	shepherd's-purse	CAPBP
<i>Chenopodium album</i>	fat hen	CHEAL
<i>Galium aparine</i>	bedstraw	GALAP
<i>Galinsoga parviflora</i>	smallflower galinsoga	GASPA
<i>Geranium pusillum</i>	smallflower geranium	GERPU
<i>Lamium purpureum</i>	red deadnettle	LAMPU
<i>Matricaria chamomilla</i>	wild chamomile	MATCH
<i>Matricaria inodora</i>	scentless chamomile	MATIN
<i>Matricaria maritima</i>	false mayweed	MATMA
<i>Fallopia convolvulus</i>	wild buckwheat	POLCO
<i>Polygonum lapathifolium</i>	pale smartweed	POLLA
<i>Stellaria media</i>	common chickweed	STEME
<i>Thlaspi arvense</i>	field pennycress	THLAR
<i>Veronica persica</i>	persian speedwell	VERPE
<i>Viola arvensis</i>	field pansy	VIOAR
<b>moderately susceptible 70-84.9%</b>		
<i>Elymus repens</i>	quackgrass	AGRRE
<i>Solanum nigrum</i>	black nightshade	SOLNI
<b>moderately tolerant 60 -69.9%</b>		
<i>Convolvulus arvensis</i>	field bindweed	CONAR

For the following weeds: GASPA, MATCH, MATMA, MERAN, and STEME, which are less damaging to maize crops, a lower number of trials (2 instead of 3 efficacy trials) was accepted, due to the fact that the results of the trials were consistent and the product achieved a very high efficacy of -100% or 98-99%.

For *Polygonum lapathifolium* (POLLA), which has to be considered as a species of high damage to maize, the efficacy in tested in a smaller number of trials (3 trials) was 99-100%, therefore such high efficacy as well as the consistency of the test results in the submitted reports were indications for a positive assessment of the efficacy of the product against this weed.

CONAR showed week (moderately tolerant) susceptibility on A18385B at dose rate 0,4 kg/ha and 0,5 kg/ha.

What is more, A18385B showed less consistent control against AGRRE, ECHCG, SOLNI. Additionally some trials for GERPU and VERPE were excluded by the Applicant with information about resistance occurrence. Regarding the above-mentioned weeds, it can be concluded that in some cases it may turn out to be MS, MT or even T.

Regarding the application of the product at 0,4kg/ha and 0,5 kg/ha, the higher of the doses (0,5 kg/ha) should be used in the case of higher weed density and when applying the product to weeds at a higher development stage. In addition to this, the product at the higher dose gave better results in the control of *Solanum nigrum*, a species that is highly damaging to maize.

### Effects on yield and quality

21 crop tolerance trials were conducted to assess the absence of adverse effects on the yield quantity and quality of maize following an application of A18385B.

Overall it can be concluded from the results of the trials reported in the Biological Assessment Dossier that A18385B applied at the single recommended rate of 0.5 kg/ha up to the double rate of 1.0 kg/ha do not cause any reductions in yield or quality of maize grown for grain or silage and has no negative effect on the different yield quality parameters measured in maize crops.

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

A18385B is a mixture of three active substances.

#### **Mode of action**

**Dicamba** is classified by HRAC within group O (Synthetic auxins). It belongs to the chemical group of benzoic acids.

Dicamba acts as auxin agonist and binds competitively to receptors of indoleacetic acid (IAA), thus leading to IAA increased concentration in meristematic tissues. This initiates a chain of events that deregulate plant cell growth, elongation and differentiation. First visible symptoms are expressed in sensitive species in a range from 2 days to several weeks, especially depending weather and plant growth stage.

**Nicosulfuron and prosulfuron** are classified by HRAC within Group B (Inhibition of the acetolactate synthase enzyme (ALS)) and belong to the chemical class of sulfonylureas. Nicosulfuron and prosulfuron inhibit the acetolactate synthase enzyme (ALS enzyme) which catalyses the first phase of the biosynthesis of the branched chain amino acids (*e.g.* valine, leucine and isoleucine). The absence of essential amino acids decreases the cellular division; susceptible plants stop growing a few hours after the treatment. Injury symptoms appear only several days after treatment and the complete death happens one or two weeks later.

#### **Resistance risk assessment with unrestricted use pattern**

The unrestricted use pattern for A18385B, in the absence of any resistance risk, would be application of the label dose post-emergence to crop and weeds. The product would be used tank mixed with an oil-based adjuvant in all label crops and with no other methods of weed management employed.

#### **Acceptability of the resistance risk**

The unmodified risk is the risk of practical resistance (inherent risk combined with agronomic risk) under “unrestricted” conditions of A18385B use, *i.e.* when A18385B is used as proposed for registration to achieve the optimum weed control.

#### **Considerations:**

- The risk inherent in nicosulfuron and prosulfuron can be assumed to correspond to that of other compounds in HRAC Group B (medium to high)
- The risk inherent in dicamba can be considered to be low to medium
- In Europe, the risk of resistance to A18385B inherent in maize weed species can be considered to be medium to high for grass weeds and low to medium for broadleaved weeds
- The agronomic risk of evolving weed resistance following A18385B use can be considered to be low, with respect to the above good agricultural practices

The risk of the target weed species developing resistance to an active ingredient within A18385B can be considered acceptable, if A18385B is used according to the label instructions.

#### **Resistance Management Strategy**

As the resistance risk assessment demonstrates that the unmodified risk of resistance to A18385B can be considered acceptable (when A18385B is used according to the label instructions), there is no restriction proposed on the A18385B use.

If considered appropriate locally, the product label could provide general advice to minimize the potential

for the development of herbicide resistant weeds, e.g. proposed EHRAC Stewardship Guidance for Herbicide Labels as follows:

*General principles of herbicide resistance management:*

- *Apply integrated weed management practices. Use multiple herbicide modes-of-actions with overlapping weed spectrums in rotation, sequences or mixtures*
- *Use the full recommended herbicide rate and proper application timing for the hardest to control weed species present in the field*
- *Scout fields after herbicide application to ensure control has been achieved. Avoid allowing weeds to reproduce by seed or to proliferate vegetatively*
- *Monitor site and clean equipment between sites*

*For annual cropping situations also consider the following:*

- *Start with a clean field and control weeds early by using a burndown treatment or tillage in combination with a pre-emergence residual herbicide as appropriate*
- *Use cultural practices such as cultivation and crop rotation, where appropriate*
- *Use good agronomic principles that enhance crop competitiveness (e.g. drilling rate)*

As the unmodified risk of resistance to A18385B can be considered acceptable (when A18385B is used according to the label instructions), no specific strategy of resistance management has to be implemented. In case weed resistance occurs, an anti-resistance strategy should be dealt with by the applicant with local authorities and defined at country level. Syngenta would propose to base any local anti-resistance strategy on the HRAC Guideline to the Management of Herbicide Resistance as listed below:

*What to do in cases of confirmed herbicide resistance:*

*In cases where a control failure has been confirmed as resistant, immediate action is required to limit further seed production of the resistant plants. The degree of the action will depend on the stage of the crop in the field and the extent of the problem.*

*Some options to consider:*

- *Eradicate the remaining weed population if growing in patches in order to limit build-up and spread of seed in the soil*
- *Limit the field to field movement of resistant populations by cleaning planting, cultivation and harvesting equipment to avoid transfer of resistant weed seed*
- *Avoid using the herbicide to which resistance has been confirmed unless used in conjunction with herbicides having a different mode of action, active on the resistant weed population*
- *If the resistant population is widespread, consider grazing the crop or cut for feed being careful not to transfer resistant seed via manure*
- *Select these fields for rotation or set aside for the following cropping season*
- *Seek advice to assist in the long-term planning of weed control in these fields*

*Once resistant weed numbers are at a controllable level, implementation of an integrated weed management system as outlined in the EHRAC Stewardship Guidance for Herbicide Labels will ensure that crops can continue to reach high levels of productivity in the fields in question.*

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

Crop phytotoxicity was evaluated in specific weed-free trials, where A18385B was applied at the single dose rate of 0.5 kg/ha and at the double dose rate of 1.0 L/ha. All applications were made at post-emergent timings (BBCH 12-18 of the crop).

Regular assessments of phytotoxicity were also performed in efficacy trials and combining this data with the crop tolerance trials, present a detailed analysis of the crop safety of A18385B.

The results show that A18385B at the target rate is generally tolerated well by maize. In 51 of 54 trials no clearly visible (< 5 %) adverse effects caused by the target rate of A18385B were observed. Phytotoxicity symptoms in the range of maximum >5 to 15 % were observed in 6 trials. In 1 efficacy trial the maximum assessed effects were 20 %. Symptoms occurred as discolouration and growth inhibition (height reduction). While the discolouration symptoms were transient and disappeared over time, growth inhibition tended to persist throughout the season. In the cases of observed phytotoxicity, yield, taken in the crop safety trials, was not reduced significantly by A18385B, if applied at the target rate.

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

#### **Impact on succeeding crops**

Based on the calculations of the Toxicity Exposure Ratios (TERs) of prosulfuron and nicosulfuron, the following can be concluded for A18385B:

- The only secure option for an early replacement of maize treated with A18385B is maize. Nevertheless, after deep soil cultivation (ploughing) peas, oilseed rape, winter wheat and rye grass may be sown as replacement crops beyond 14 days after application.
- All the tested crops are options for replanting within a normal crop rotation situation. For oilseed rape, winter wheat and rye grass sown in the early autumn, deep soil cultivation may be recommended to secure the crops safety.

No accumulation of dicamba in the field is expected given its rapid degradation in laboratory studies.

However practical experiences with post-em applications to maize of existing products containing solo dicamba, prosulfuron and nicosulfuron have shown that some phytotoxicity may occur on following or replacement crop; especially under adverse conditions for rapid degradation in soil (such as poor soil, low pH, dry cold winter etc.). However, these effects are usually transient and lead to no reductions in the yield or quality of succeeding crops.

Similar effects may be observed for A18385B applied at the recommended rate of 0.5 kg/ha, as the rate per hectare of dicamba, prosulfuron and nicosulfuron are similar to the registered rates of the solo products.

In conclusion, after practical experience with existing products containing dicamba, nicosulfuron or prosulfuron, the following and replacement crop restrictions for A18385B are recommended to be similar to the existing local product labels of the solo products.

A18385B applied according to recommendations does not lead to unacceptable risk to succeeding crops.

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

#### **3.4.1 Analytical method for the formulation**

An analytical method has been developed for the determination of the active substances prosulfuron, dicamba and nicosulfuron in A18385B. Prosulfuron, dicamba and nicosulfuron are determined simultaneously by HPLC on a Nucleosil C18 column (column length 75 mm, column internal diameter 4.6 mm). Elution was by a 0.1% aqueous phosphoric acid and acetonitrile gradient. Detection was spectrophotometrically by an UV detector operating at 240 nm. Quantification was obtained by comparing peak areas of test samples with the areas from calibrated analytical standard solutions (external standard). Full validation of the method SF-570/1 has been conducted. The method SF-570/1 is suitable for the specific, accurate and precise determination of prosulfuron, dicamba and nicosulfuron in A18385B.

No CIPAC method is available for the determination of prosulfuron, dicamba and nicosulfuron in mixed



WG formulations such as A18385B.

No CIPAC method is available for the determination of prosulfuron in WG formulations.

A CIPAC method is available for the determination of nicosulfuron in WG formulations. Nicosulfuron is determined by high performance liquid chromatography using a Zorbax® SB column, UV detection at 245 nm and internal standardisation (3-methyl-1,1-diphenylurea). The active substance content is quantified using a calibration curve. (CIPAC Handbook M, page 21).

A CIPAC method is available for the determination of dicamba in WG formulations. Dicamba is dissolved in methanol and determined by high performance liquid chromatography on a reversed phase column (RP18) using UV detection and external standardisation. (CIPAC Handbook K, page 32).

### **3.4.2 Analytical methods for residues**

The zRMS agrees with all the applicant conclusions on residue analytical methods. In the context of the authorisation request the required methods are available and considered adequate.

#### **Pre-authorization data;**

##### Prosulfuron

- No specific analytical methods for the generation of pre-authorization data for prosulfuron in soil, water and air (in support of environmental fate studies)
- No specific analytical methods were used to support the efficacy data generated on this product.
- No analytical methods were used to support the toxicology data generated on this product.
- No specific operator, worker, resident or bystander exposure studies were conducted to support this product. Consequently, no analytical methods were required.
- Methods for plant and animal products (residues studies): All analytical methods for prosulfuron were evaluated during the EU review and considered acceptable.
- Analytical methods were used to support the ecotoxicology data generated on this product. Those studies have not been evaluated as part of the EU assessment of prosulfuron, nicosulfuron and dicamba but was evaluated in the Central zone for authorization of A18385B and considered acceptable.
- No specific analytical methods were used to support the physical and chemical properties generated on this product.

##### Nicosulfuron

- No specific analytical methods for the generation of pre-authorization data for nicosulfuron in soil, water and air (in support of environmental fate studies)
- No specific analytical methods were used to support the efficacy data generated on this product.
- No analytical methods were used to support the toxicology data generated on this product.
- No specific operator, worker, resident or bystander exposure studies were conducted to support this product. Consequently, no analytical methods were required.
- Methods for plant and animal products (residues studies): All analytical methods for nicosulfuron were evaluated during the EU review and considered acceptable.
- No specific analytical methods were used to support the ecotoxicology data generated on this product.
- No specific analytical methods were used to support the physical and chemical properties generated on this product.

##### Dicamba

- No specific analytical methods for the generation of pre-authorization data for dicamba in soil, water and air (in support of environmental fate studies)
- No specific analytical methods were used to support the efficacy data generated on this product. No analytical methods were used to support the toxicology data generated on this product.

- No specific operator, worker, resident or bystander exposure studies were conducted to support this product. Consequently, no analytical methods were required.
- Methods for plant and animal products (residues studies): All analytical methods for dicamba were evaluated during the EU review and considered acceptable. For the additional residue trials reported in the framework of this application, residue analytical methods were used that have already been evaluated on EU level, i.e. REM 193.01 (post-registration method), P-14.063.02 or AM-0691B.
- No specific analytical methods were used to support the ecotoxicology data generated on this product.
- No specific analytical methods were used to support the physical and chemical properties generated on this product.

**Post- authorization control and monitoring data;**

Overview of residue definitions and levels for which compliance is required

Prosulfuron

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

**Table 3.4.2-1: Relevant residue definitions for monitoring/enforcement and levels for which compliance is required**

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
Plant, high water content	Prosulfuron <sup>(a)</sup>	0.01 mg/kg	MRL (Reg. (EU) No 617/2014)
Plant, high acid content		0.01 mg/kg	MRL (Reg. (EU) No 617/2014)
Plant, high protein/high starch content (dry commodities)		0.01 mg/kg	MRL (Reg. (EU) No 617/2014)
Plant, high oil content		0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Muscle	Prosulfuron	0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Milk		0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Eggs		0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Fat		0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Liver		0.05 mg/kg	MRL (Reg. (EU) No 617/2014)
Kidney		0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Soil (Ecotoxicology)	Prosulfuron	0.131 mg/kg	NOEC for soil microorganisms (nitrogen mineralisation) (EFSA, 2014)
Drinking water (Human toxicology)	Prosulfuron	0.1 µg/L	General limit for drinking water
Surface water (Ecotoxicology)	Prosulfuron	0.016 mg/L	Biomass E <sub>b</sub> C <sub>50</sub> for <i>Pseudo-kirchneriella subcapitata</i> (72 h-static) (EFSA, 2014)
Air	Prosulfuron	1 µg/m <sup>3</sup>	AOEL: 0.06 mg/kg bw/d (EFSA, 2014)
Tissue (meat or liver)	Prosulfuron	Not required	Not classified as T / T+
Body fluids		Not required	Not classified as T / T+

(a): Draft residue definition subject to the data gap on the genotoxicity of CGA150829 (EFSA, 2014)

#### Nicosulfuron

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

**Table 3.4.2-2: Relevant residue definitions for monitoring/enforcement and levels for which compliance is required**

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
Plant, high water content	Nicosulfuron	0.01 mg/kg	MRL (Reg. (EU) No 617/2014)
Plant, high acid content		0.01 mg/kg	MRL (Reg. (EU) No 617/2014)
Plant, high protein/high starch content (dry commodities)		0.01 mg/kg	MRL (Reg. (EU) No 617/2014)
Plant, high oil content		0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Plant, difficult matrices		0.05 mg/kg	MRL (Reg. (EU) No 617/2014)

Matrix	Residue definition	MRL / limit	Reference for MRL/level Remarks
(hops, spices, tea)			
Muscle	Nicosulfuron	0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Milk		0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Eggs		0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Fat		0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Liver, kidney		0.02 mg/kg	MRL (Reg. (EU) No 617/2014)
Soil (Ecotoxicology)	Nicosulfuron	>1000 mg/kg (dry weight)	LC <sub>50</sub> for <i>Eisenia fetida</i> (acute 14 days) (EFSA, 2007)
Drinking water (Human toxicology)	Nicosulfuron	0.1 µg/L	general limit for drinking water
Surface water (Ecotoxicology)	Nicosulfuron	1.7 µg/L	EC <sub>50</sub> for <i>Lemna gibba</i> (7 day frond count) (EFSA, 2007)
Air	Nicosulfuron	1.2 µg/m <sup>3</sup>	AOEL: 0.8 mg/kg bw/d (EFSA, 2007)
Tissue (meat or liver)	Nicosulfuron	Not required	Not classified as T / T+
Body fluids		Not required	Not classified as T / T+

#### Dicamba

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

In the Draft Assessment Report (Denmark, 2007), parent dicamba was proposed as residue definition for both plants and animals. In their Conclusion (EFSA, 2011), EFSA proposed to define the residue for monitoring as dicamba and its salts (free and conjugated). However, MRLs are currently set for dicamba.

**Table 3.4.2-3: Relevant residue definitions for monitoring/enforcement and levels for which compliance is required**

Matrix	Residue definition	MRL / limit	Reference for MRL level/ Remarks
Plant, high water content	Dicamba	0.05 mg/kg	MRL (Reg. (EU) No 2015/845)
Plant, high acid content		0.05 mg/kg	MRL (Reg. (EU) No 2015/845)
Plant, high protein/high starch content (dry commodities)		0.05 mg/kg	MRL (Reg. (EU) No 2015/845)
Plant, high oil content		0.05 mg/kg	MRL (Reg. (EU) No 2015/845)
Plant, difficult matrices (hops, spices, tea)		0.05 mg/kg	MRL (Reg. (EU) No 2015/845)
Muscle	Dicamba	0.05 mg/kg (poultry 0.02 mg/kg)	MRL (Reg. (EU) No 2015/845)
Milk		0.2 mg/kg	MRL (Reg. (EU) No 2015/845)
Eggs		0.05 mg/kg	MRL (Reg. (EU) No 2015/845)
Fat		0.07 mg/kg	MRL (Reg. (EU) No 2015/845)

Matrix	Residue definition	MRL / limit	Reference for MRL level/ Remarks
		(poultry 0.04)	
Liver, kidney		0.7 mg/kg (poultry 0.07)	MRL (Reg. (EU) No 2015/845)
Soil (Ecotoxicology)	Dicamba (Banvel 480 SL)	> 480 mg/kg (dry weight)	LC <sub>50</sub> for <i>Eisenia fetida</i> (acute 14 days) (EFSA, 2011)
Drinking water (Human toxicology)	Dicamba	0.1 µg/L	General limit for drinking water
Surface water (Ecotoxicology)	Dicamba	1.8 mg/L	Biomass E <sub>b</sub> C <sub>50</sub> for <i>Skeletonema costatum</i> (72 h-static) (EFSA, 2011)
Air	Dicamba	Open (21 µg/m <sup>3</sup> not accepted)	AOEL: 0.3 mg/kg bw/d (EFSA, 2011)
Tissue (meat or liver)	Dicamba	Not required	Not classified as T / T+
Body fluids	-	Not required	Not classified as T / T+

**Methods for plant matrices:** All analytical methods are active substance data and were evaluated during the EU review of prosulfuron, nicosulfuron and dicamba. Additional data on methods and validation has been provided for nicosulfuron on plants with high water content, high protein/high starch content (dry) and other (maize stover/straw).

**Methods for animal matrices:** All analytical methods are active substance data and were evaluated during the EU review of prosulfuron, nicosulfuron and dicamba. Additional data on methods and validation has been provided for dicamba for milk, egg, muscle, fat and kidney (liver); the study was not evaluated at the time of the peer review.

**Methods for soil, water and air:** All analytical methods are active substance data and were evaluated during the EU review of prosulfuron, nicosulfuron and dicamba. Additional data on methods and validation has been provided for dicamba, as the EFSA conclusion (EFSA Journal 2011;9(1):1965) has identified a data gap as the air method was not fully validated. All data are considered adequate.

**Methods for body fluids and tissues:** Prosulfuron, nicosulfuron and dicamba are not classified as toxic or highly toxic, therefore analytical methods for the determination of residues in body fluids and tissue are not required.

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

According to Regulation 1272/2008 as amended, the proposed toxicological classification for A18385B is:

**Hazard class, category:** Eye Irrit. 2  
**H319:** Causes serious eye irritation

As a plant protection product, the instructions for use should be followed to avoid risks to man and the environment.

No unacceptable risk for operators, workers, bystanders and residents was identified when the product is used as intended. No specific PPE is necessary.

Due to the classification of the product - Wear eye protection/face protection when handling the product.

#### 3.5.1 Acute toxicity

A summary of the toxicological evaluation for A18385B is given in the following table:

Type of test, species, model system (Guideline)	Result	Classification (acc. to the criteria in Reg. 1272/2008)
LD <sub>50</sub> oral, rat (OECD 425 (2008); EPA OPPTS 870.1100 (2002))	> 2000 mg/kg bw	None
LD <sub>50</sub> dermal, rat (OECD 402 (1987); OPPTS 870.1200 (1998); EC 440/2008 (2008))	> 2000 mg/kg bw	None
LC <sub>50</sub> inhalation (Calculation method)	8.1 mg/L/4h	None
Skin irritation, rabbit skin (OECD 404 (2002); OPPTS 870.2500 (1998); EC No 440/2008, B.4 (2008))	Non-irritant	None
Eye irritation, rabbit eye (OECD 405 (2012); EPA OPPTS 870.2400 (1998); EC No 440/2008, B.5 (2008); Directive 2004/73/EC B.5 (L 152 2004 29th April))	Irritant	Eye Irrit. 2, H319
Skin sensitisation, mouse (OECD 429 (2010); EC No 440/2008 of 30 May 2008, B.42, LLNA)	Non-sensitising	None
Supplementary studies for combinations of plant protection products	No data – not required	

No data on dermal absorption for prosulfuron, nicosulfuron and dicamba in A18385B are available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the core dossier Part B6.

### **Toxicological Evaluation of the Groundwater Metabolites**

#### **Prosulfuron metabolites**

Data and toxicological studies on metabolites CGA349707, CGA159902, CGA300406, CGA150829, CGA325025, SYN542604 and SYN547308 with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were submitted.

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

The outcome of the assessment shows that all metabolites can be considered to be non-relevant in the context of the criteria outlined in the “Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated Under Council Directive 91/414/EEC. (SANCO/221/2000-rev.10; 25 February 2003).

#### **Nicosulfuron metabolites**

The relevance of the metabolites was already assessed for the authorization of the product A18385B for the GAP and groundwater scenarios considered in this dRR. Hence, a new assessment according to Step 1-5 of guidance document SANCO/221/2000 –rev.10 is not required.

The outcome of the assessment shows that all metabolites can be considered to be non-relevant in the context of the criteria outlined in the “Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated Under Council Directive 91/414/EEC. (SANCO/221/2000-rev.10; 25 February 2003).

#### Dicamba metabolites

All metabolite concentrations are predicted to stay below 0.001µg/L – no groundwater assessment is required.

### **3.5.2 Operator exposure**

Operator exposure for use of A18385B was modelled using EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection product [EFSA Journal 2014;12(10):3874 (55pp.)].

According to the exposure calculations, it can be concluded that the risk for the operator using A18385B on maize is acceptable without using PPE.

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses, a study to provide measurements of operator exposure was not necessary and was therefore not performed.

Due to the classification of the product - Wear eye protection/face protection when handling the product.

### **3.5.3 Worker exposure**

Worker exposure for A18385B was modelled using EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection product [EFSA Journal 2014;12(10):3874 (55pp.)].

According to the exposure calculations, it is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing when re-entering crops treated with A18385B. As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

No specific PPE is necessary.

### **3.5.4 Bystander and resident exposure**

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

Consequently, the evaluation for A18385B in Section B6 provides a first tier assessment based on the EFSA guidance [EFSA Journal 2014;12(10):3874 (55pp.)] and additionally an assessment according to the German guidance paper, (see Martin *et al.* (2008)<sup>1</sup>).

According to the exposure calculations of both models, it is concluded that there is no undue risk to any bystander and resident after exposure to A18385B. This has no labelling implications. However, according to EFSA opinion the use of the German guidance paper is not scientifically supported any longer, since the predictions are considered underestimated.

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for prosulfuron, nicosulfuron and dicamba will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

No specific PPE is necessary.

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<sup>1</sup> Martin S. *et al.* (2008): Guidance for Exposure and Risk Evaluation for Bystanders and Residents Exposed to Plant Protection Products During and After Application; J. Verbr. Lebensm. 3 (2008): 272-281 Birkhäuser Verlag Basel and Bundesanzeiger (BANz), 06 January 2012, Issue No. 4, pp. 75-76

## **Combined exposure Assessment of prosulfuron, nicosulfuron and dicamba in A18385B**

The product is mixture of three active substances.

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

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

The Hazard Index is  $< 1$ . Thus, combined exposure to all active substances in A18385B is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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

The conclusions below are provided by the applicant. The zRMS agrees with all of them. The data provided are sufficient for granting the requested authorisation. The proposed use in maize can be accepted. The relevant MRL are not expected to be exceeded. The use of the product (A18385B) does not lead to unacceptable risk for consumers when applied according to the recommendations.

#### **3.6.1 Residues**

##### **Prosulfuron**

For the uses proposed for prosulfuron in A18385B on maize, all relevant residue data and assessments are provided.

##### **Stability of residues during storage and in sample extracts:**

The potential for degradation of residues during storage has been previously assessed in the framework of the peer review for prosulfuron. No new data related to the stability of residues during storage of samples were therefore provided. Stability of residues in sample extracts is confirmed by the procedural recovery samples analysed as part of each analytical batch of residue samples. Data are expected to be within the usual limits of recovery as defined within analytical method validation and fully support the residue data presented in this submission.

##### **Nature of residues in plants, livestock and processed commodities:**

No new data related to the nature of residues in primary or rotational crops, processed commodities or livestock are submitted in the framework of this application. The available data sufficiently addresses the proposed uses of prosulfuron in the product A18385B.

##### **Magnitude of residues in plants:**

Maize is a major crop in both northern and southern Europe and therefore normally requires eight trials in each region to support an EU MRL (SANCO 7525/VI/95 rev. 10.3). A total of 19 trials are available from the first evaluation of prosulfuron (DAR, 1998<sup>2</sup>), 12 conducted in Northern Europe and 7 in Southern Europe. An additional 31 trials (16 N-EU, 15 S-EU) were submitted for the Annex I renewal of prosulfuron (RAR, 2014; Final Addendum<sup>3</sup>). However, the Rapporteur Member State did not consider

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<sup>2</sup> Draft assessment report on the active substance prosulfuron prepared by the rapporteur Member State France in the framework of Council Directive 91/414/EEC, December 1998.

<sup>3</sup> Final addendum to the renewal assessment report on the active substance prosulfuron prepared by the rapporteur Member State France in the framework of Council Regulation (EU) No 1141/2010, June 2014.



these new trials in the re-evaluation as they do not provide further information to the residue situation on maize.

In all maize whole plant, leaf, stalk, fodder, cob and grain specimens collected in these trials, residues of prosulfuron were below the level of analytical quantification (<0.01 or <0.02 mg/kg). It is therefore concluded that sufficient data are available which show that no exceedance of the existing MRL will occur. The uses on maize are considered acceptable.

#### **Magnitude of residues in livestock:**

The use of A18385B may result in residues of prosulfuron in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. Livestock intake calculations (Animal Model 2017) and feeding studies undertaken are provided. The median and maximum dietary burdens were therefore calculated for different groups of livestock. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues in commodities of animal origin is not necessary.

#### **Magnitude of residues in processed commodities:**

Data/information on processing studies was reviewed during the approval of prosulfuron and considered sufficient. Quantifiable residues of prosulfuron are not expected in the treated crops and the TMDI is <10%). Thus, there is no need to investigate the effect of industrial and/or household processing. No further studies have been performed.

#### **Magnitude of residues in representative succeeding crops:**

The crops under consideration can be grown in rotation. Considering available data dealing with nature of residues and the confined rotational crop study, prosulfuron residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that A18385B is applied in compliance with the GAPs supported for this submission. No further study dealing with magnitude of residues in succeeding crops is needed.

#### **Nicosulfuron**

For the uses proposed for nicosulfuron in A18385B on maize, all relevant residue data and assessments are provided.

#### **Stability of residues during storage and in sample extracts:**

The storage stability of nicosulfuron has been investigated in different groups, including commodities with high water and high starch content during the EU peer review. Sufficient stability has been demonstrated to support the residue data presented in the submission. A residue definition for animal products has not been proposed, since the uses of nicosulfuron will not lead to significant residues in any edible animal tissue or milk. Thus, no stability data in commodities of animal origin are required.

Stability of residues in sample extracts is confirmed by the procedural recovery samples analysed as part of each analytical batch of residue samples. Data are expected to be within the usual limits of recovery as defined within analytical method validation and fully support the residue data presented in this submission.

#### **Nature of residues in plants, livestock and processed commodities:**

No new data related to the nature of residues in primary or rotational crops, processed commodities or livestock are submitted in the framework of this application. The available data sufficiently addresses the proposed uses of nicosulfuron in the product A18385B.

#### **Magnitude of residues in plants:**

Maize is a major crop in both northern and southern Europe and therefore normally requires eight trials in each region to support an EU MRL (SANCO 7525/VI/95 rev. 10.3). A total of 33 trials are available from

the first evaluation of nicosulfuron (DAR, 2006<sup>4</sup>), 18 conducted in Northern Europe and 15 in Southern Europe. No additional trials have been performed.

In all maize whole plant (fodder), ears and grain specimens collected in these trials, residues of nicosulfuron were below the level of analytical quantification (<0.01 mg/kg), except for one whole plant sample each in Northern and Southern Europe with residues of 0.015 and 0.013 mg/kg, respectively. It is therefore concluded that sufficient data are available which show that no exceedance of the existing MRL will occur. The uses of A18385B on maize are considered acceptable.

#### **Magnitude of residues in livestock:**

The use of A18385B may result in residues of nicosulfuron in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. Livestock intake calculations (Animal Model 2017) and feeding studies undertaken are provided. The median and maximum dietary burdens were therefore calculated for different groups of livestock. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues in commodities of animal origin is not necessary.

#### **Magnitude of residues in processed commodities:**

Data/information on processing studies was reviewed during the approval of nicosulfuron and considered sufficient. Quantifiable residues of nicosulfuron are not expected in the treated crops and the TMDI is <10%). Thus, there is no need to investigate the effect of industrial and/or household processing. No further studies have been performed.

#### **Magnitude of residues in representative succeeding crops:**

The crops under consideration can be grown in rotation. Considering available data dealing with nature of residues and the confined rotational crop study, nicosulfuron residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that A18385B is applied in compliance with the GAPs supported for this submission. No further study dealing with magnitude of residues in succeeding crops is needed.

#### **Dicamba**

For the uses proposed for dicamba in A18385B on maize, all relevant residue data and assessments are provided.

#### **Stability of residues during storage and in sample extracts:**

The storage stability of dicamba and its relevant metabolite 5-OH-dicamba has been investigated in different groups, including commodities with high water and high starch content and animal matrices (dicamba only) in the peer review. No new data related to the stability of residues during storage of samples were therefore provided. Stability of residues in sample extracts is confirmed by the procedural recovery samples analysed as part of each analytical batch of residue samples. Data are expected to be within the usual limits of recovery as defined within analytical method validation. For animal matrices stability of dicamba and metabolite DCSA (NOA414746) were reanalysed and confirmed using the ILV of analytical method GRM022.03A.

#### **Nature of residues in plants, livestock and processed commodities:**

No new data related to the nature of residues in primary or rotational crops, processed commodities or livestock are submitted in the framework of this application. The available data sufficiently addresses the proposed uses of dicamba in the product A18385B.

#### **Magnitude of residues in plants:**

Maize is a major crop in both northern and southern Europe and therefore normally requires eight trials in each region to support an EU MRL (SANCO 7525/VI/95 rev. 10.3). A total of 18 trials are available from

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<sup>4</sup> Draft assessment report on the active substance nicosulfuron prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, June 2006.

the first evaluation of dicamba (DAR, 2007<sup>5</sup>), 10 conducted in Northern Europe and 8 in Southern Europe. Only 13 trials were considered for MRL derivation by the rapporteur Member State and EFSA (9 NEU and 4 SEU). An additional 4 SEU trials were submitted with the MRL Compilation dossier for dicamba. These trials were performed with a lower application rate of about 0.280 kg a.s./ha, in compliance with the most recent overall cGAP.

In all maize grain specimens collected in these trials, residues of dicamba were below the level of analytical quantification (<0.01 or <0.05 mg/kg). It is therefore concluded that sufficient data are available which show that no exceedance of the existing MRL will occur. The uses of dicamba in A18385B on maize are considered acceptable.

#### **Magnitude of residues in livestock:**

The use of A18385B may result in residues of dicamba in animal feed items, therefore the possible transfer of residues in animal commodities from the proposed uses should be considered. Livestock intake calculations (Animal Model 2017) and feeding studies undertaken are provided.

The median and maximum dietary burdens were therefore calculated for different groups of livestock. The calculated dietary burdens for ruminants and pigs were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore only required in these groups of livestock.

Livestock feeding studies for ruminants, pig and poultry are available and were evaluated during the peer-review process. The uses do not modify the theoretical maximum daily intake for animals, while the new mode of calculation does, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

#### **Magnitude of residues in processed commodities:**

Data/information on processing studies was reviewed during the approval of active substance(s) and considered acceptable. As quantifiable residues of dicamba are not expected in the treated crops and the TMDI is <10%, there is no need to investigate the effect of industrial and/or household processing. However, processing studies are required to cover industrial and domestic processes commonly applied to cereal grains. Representative crop processing studies have been carried out to cover industrial and domestic processes commonly applied to cereal grains.

#### **Magnitude of residues in representative succeeding crops:**

The crops under consideration can be grown in rotation. Considering available data dealing with nature of residues and the confined rotational crop study, dicamba residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that A18385B is applied in compliance with the GAPs supported for this submission.

### **3.6.2 Consumer exposure**

#### **Prosulfuron**

The consumer risk assessment was performed using the EU MRLs for prosulfuron, published in Annexes of Reg. (EU) No 617/2014. It can be concluded that the use of product A18385B does not lead to unacceptable acute and chronic risk for consumers when applied according to the recommendations.

A summary of the calculation for the consumer exposure is presented below:

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	Not shown, please refer to IEDI calculations
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	7% (based on NL toddler)
TESTI (% ARfD) according to EFSA PRIMo rev. 3.1	Maize/oil: 0.2% (based on NL toddler) Milk: 2% (based on UK infant) Other animal matrices: ≤0.8%

<sup>5</sup> Draft assessment report on the active substance dicamba prepared by the rapporteur Member State Denmark in the framework of Council Directive 91/414/EEC, February 2007.

### Nicosulfuron

The consumer risk assessment was performed using the EU MRLs for nicosulfuron, published in Annexes of Reg. (EU) No 617/2014. It can be concluded that the use of product A18385B does not lead to unacceptable acute and chronic risk for consumers when applied according to the recommendations.

A summary of the calculation for the consumer exposure is presented below:

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	Not shown, please refer to IEDI calculations
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	0.1% (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1	Not applicable

### Dicamba

The consumer risk assessment was performed using the actual EU MRLs based on EFSA (2011<sup>6</sup>) and the Annex II dossier of dicamba. It can be concluded that the use of product A18385B does not lead to unacceptable acute and chronic risk for consumers when applied according to the recommendations.

A summary of the calculation for the consumer exposure is presented below:

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	Not conducted as the proposed EU MRL values for dicamba are based on the residues of the parent compound only.
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	0.8% (based on GEMS/Food G08)
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1	Maize/oil: 0.2% (based on NL toddler) Bovine edible offals: 0.6% (based on UK infant) Other animal matrices: ≤0.4%

### Combined risk assessment

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

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

The product is a mixture of three active substances and for two of them an acute reference dose has been allocated. Therefore, combined acute exposure can be considered.

The calculated Hazard Index is <1. Thus combined exposure to all active substances in A18385B is not expected to present a consumer risk. No further refinement of the assessment is required.

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

### Prosulfuron

All studies on the aerobic and anaerobic degradation rates in soil of prosulfuron and its relevant metabolites, studies on the field dissipation rates, studies on adsorption/ desorption and studies on the degradation of prosulfuron and its metabolites in water/sediment systems are considered to be data provided in support of the active substance. All relevant detailed experimental information was evaluated during the EU review (Prosulfuron, EFSA Journal 2014;12(9): 3815<sup>7</sup> and Prosulfuron, EFSA Journal 2020;18(7):6181).

<sup>6</sup> Scientific support for preparing an EU position in the 43rd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2011;9(9):2360. [123 pp.] doi:10.2903/j.efsa.2011.2360.

<sup>7</sup> EFSA Journal, 2014: Conclusion on the peer review of the pesticide risk assessment of the active substance prosulfuron. EFSA Journal 2014;12(9):3815.

In the review report for the active substance prosulfuron (SANTE/10682/2015 Rev 3, 24. January 2017) it is referred to the EFSA conclusion of prosulfuron that considered the groundwater risk assessment for the unidentified metabolite M17 as not finalized (EFSA Journal 2020;18(7):6181).

The expert meeting acknowledged the extensive work undertaken in trying to identify M17 and agreed that it was technically not feasible to identify the metabolite. However, information to address the groundwater leaching risk was still expected. An initial assessment has been made to provide a quantitative groundwater assessment for M17 using assumptions and a weight of evidence of information available to aid decision making.

Field dissipation data submitted during the EU review did not comply latest guidance. Therefore new field studies have been performed in compliance with latest guidance (EFSA, 2014a)<sup>8</sup>; new kinetic evaluation is presented (Hardy & Jastrebski 2015 a and b). New degradation and adsorption studies (Patel (2014) and Crabtree (2014)) were generated for the metabolite SYN547308 and are provided with this dossier.

### **Nicosulfuron**

All studies on the aerobic and anaerobic degradation rates in soil of nicosulfuron and its metabolites, studies on the field dissipation rates, studies on adsorption/ desorption and studies on the degradation of nicosulfuron and its metabolites in water/sediment systems are considered to be data provided in support of the active substance. All relevant detailed experimental information was evaluated during the EU review (Nicosulfuron, EFSA Scientific Report (2007);120, 1-91<sup>9</sup>). Further studies on adsorption/desorption were not necessary; nevertheless additional data for the refinement of the risk assessment were needed (Graham and Strachan, 2008).

### **Dicamba**

All studies on the aerobic and anaerobic degradation rates in soil of dicamba and its metabolites, studies on the field dissipation rates, studies on adsorption/ desorption and studies and on the degradation of dicamba and its metabolite in water/sediment systems are considered to be data provided in support of the active substance. All relevant detailed experimental information was evaluated during the EU review (Dicamba, EFSA Journal 2011;9(1):1965<sup>10</sup>).

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

### **Prosulfuron**

EU agreed endpoints were used for PEC<sub>s</sub> calculations of prosulfuron and their respective metabolites. Given the DT<sub>50</sub> and DT<sub>90</sub> of prosulfuron are < 100 d and 365 d respectively, calculations to estimate potential accumulation of prosulfuron was not undertaken. The potential accumulation of prosulfuron metabolites (i.e. CGA150829, CGA159902, SYN542604, CGA349707 and SYN547308 in soil were conducted for these metabolites due to maximum DT<sub>50</sub> > 100 days or DT<sub>90</sub> > 1000 days.

PEC soil together with the PEC<sub>s,plateau</sub> and PEC<sub>s,accumulation</sub>, where relevant, calculations are reported in section B8.

### **Nicosulfuron**

EU agreed endpoints were used for PEC<sub>s,ini</sub> calculations of nicosulfuron and their respective metabolites. Given the DT<sub>50</sub> of nicosulfuron are < 100 d respectively, calculations to estimate potential accumulation of nicosulfuron was not undertaken. The PEC of HMUD, AUSN, ADMP, UCSN and ASDM in soil (PEC<sub>s,ini</sub>) has been calculated from the maximum initial PEC<sub>s,ini</sub> of nicosulfuron. Additionally, calculations of the potential accumulation of nicosulfuron metabolites AUSN, UCSN and ASDM in soil

<sup>8</sup> EFSA (2014a): EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT<sub>50</sub> values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal (2014);12(5):3662, 37pp.

<sup>9</sup> EFSA Journal, 2007: Conclusion on the peer review of the pesticide risk assessment of the active substance nicosulfuron. EFSA Scientific Report 2007, 120. 1-91.

<sup>10</sup> EFSA Journal 2011: Conclusion on the peer review of the pesticide risk assessment of the active substance dicamba. EFSA Journal 2011;9(1):1965.

(PEC<sub>s, accumulation</sub>) were conducted due to maximum DT<sub>50</sub> > 100 days.

PEC soil together with the PEC<sub>s,plateau</sub> and PEC<sub>s,accumulation</sub>, where relevant, calculations are reported in section B8.

### Dicamba

EU agreed endpoints were used for PEC<sub>s</sub> calculations of dicamba and the respective metabolite DCSA. As established in the EU review, only initial PEC<sub>s,ini</sub> values for dicamba were calculated and used in the risk assessment. No accumulation of dicamba in the field can be expected given the rapid degradation observed in laboratory studies.

The PEC of DCSA in soil (PEC<sub>s,ini</sub>) has been assessed based on the worst case parent PEC<sub>s,ini</sub> for dicamba. Given the extremely low maximum residue levels, no long term PEC calculations were undertaken for the metabolites of dicamba.

### A18385B

The PECs calculated for A18385B was also submitted. Formulation components other than the active substances are assumed to dissipate rapidly in the environment, therefore only an initial concentrations was calculated.

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

### Prosulfuron

The modelling of PEC<sub>gw</sub> has been performed for the standard FOCUS scenarios to obtain outputs from the FOCUS PEARL (v4.4.4), FOCUS PELMO (5.5.3) and FOCUS MACRO (v. 5.5.3) models considering the proposed use rates in the GAP and yearly application of the product A18385B in maize.

Simulations were carried out using the FOCUS standard crop scenarios for maize.

For prosulfuron, a tiered approach was undertaken. The degradation and dissipation of prosulfuron was studied in soil under laboratory and field conditions, respectively. Both was considered in modelling and simulated separately as Tier 1 and Tier 2.

- In Tier 1 the geometric mean laboratory DegT<sub>50</sub> (20°C/Q<sub>10</sub> = 2.58, pF2) of 62.1 days was used in combination with the arithmetic mean sorption parameters as stated in the EU review of prosulfuron.
- In Tier 2 the geometric mean field DT<sub>50</sub> (20°C/Q<sub>10</sub> = 2.58, pF2) of 20.8<sup>11</sup> days was used in modelling in combination with different refinement options as shown in the table below:

Tier		Refinement options used for PEC <sub>gw</sub> modelling
Tier 1, lab DegT <sub>50</sub> (62.1 d)		PUF = 0
Tier 2, field DT <sub>50</sub> (18.7 d)	a	PUF = 0.15, application every year
	b	PUF = 0.15, application every second year

The PEC<sub>gw</sub> for prosulfuron in leachate at 1 m soil depth following 20 years of use in maize are > 0.1 µg/L in several scenarios in Tier 1. In Tier 2 the PEC<sub>gw</sub> was < 0.1 µg/L for all scenarios using the geometric field DT<sub>50</sub> in combination with EU the agreed sorption parameters, i.e. geometric mean K<sub>FOC</sub> / K<sub>FOM</sub>.

<sup>11</sup> 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).

As for some of the metabolites the  $PEC_{gw}$  are above 0.1  $\mu\text{g/L}$ , the assessment of their relevance in groundwater is presented in the Section B10 of this dRR and summarized in point 3.9 of this document.

It was accepted that it was not technically feasible to identify M17. An assessment of its potential leaching was however made based on reasoned assumptions to provide a conservative worst case risk of exposure to groundwater. Details are presented in B8. It can be concluded that here is no unacceptable leaching risk to groundwater of M17.

**The maximum  $PEC_{GW}$  values for active substances were below the trigger value of 0.1  $\mu\text{g/L}$  if prosulfuron was applied every 2<sup>nd</sup> year.**

#### **Nicosulfuron**

The modelling of  $PEC_{gw}$  for nicosulfuron and its metabolites HMUD, AUSN, ADMP, UCSN, ASDM and MU-466 has been performed for the standard FOCUS scenarios to obtain outputs from the FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3 and FOCUS MACRO v5.5.3 models considering the proposed use rates in the GAP and triennial application of the product A18385B in maize.

More recently an additional soil adsorption study was undertaken by Cheminova in which adsorption to a further 10 soils was studied. Syngenta have been given access to the study summary (Graham and Strachan, 2008). With this additional study and considering all adsorption values ( $n=14$ ), the geometric mean  $K_{FOC}$  is increased to 24.6 mL/g.

Modelling has been undertaken using the revised adsorption based on the increased number of soils studied. Based on the assessment, the use of nicosulfuron is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied triennially according to the proposed use pattern of up to 50 g nicosulfuron/ha. The maximum predicted environmental concentration ( $PEC_{gw}$ ) at 1 m depth for nicosulfuron following 66 years (includes six years warm-up period) use on maize at either 40 g a.s./ha or 50 g a.s./ha with 25% foliar interception, was 0.050  $\mu\text{g/L}$  in the Hamburg scenario and was less than using the FOCUS- PEARL model and a  $DT_{50}$  of 16.4 days.

The metabolite ADMP is predicted to occur in groundwater <0.001 $\mu\text{g/L}$ , the metabolite MU-466 <0.1  $\mu\text{g/L}$  and the metabolite HMUD >0.1  $\mu\text{g/L}$  but <0.75  $\mu\text{g/L}$ . The metabolites AUSN, UCSN and ASDM are predicted to occur in groundwater at concentrations >0.75 $\mu\text{g/L}$  but <10 $\mu\text{g/L}$ .

All of the metabolites were concluded to be non-relevant. For the assessment of their relevance in groundwater refer to Section B10 of this dRR and further info are summarized in point 3.9 of this document.

**The maximum  $PEC_{GW}$  values for active substances were below the trigger value of 0.1  $\mu\text{g/L}$  if nicosulfuron was applied every 3<sup>rd</sup> year.**

#### **Dicamba**

The modelling of  $PEC_{gw}$  for dicamba and its metabolite DCSA (NOA414746) has been performed for the standard FOCUS scenarios to obtain outputs from the FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3 and FOCUS MACRO v5.5.3 models considering the proposed use rates in the GAP and triennial application of the product A18385B in maize.

Dicamba has the potential for high mobility in soil in consideration of low  $K_{FOC}$  values. However, taking into account its rapid degradation in soil, the risk to groundwater is expected to be minimal. For the major metabolite DCSA, strong adsorption to soil combined with a quick degradation indicate a low potential for movement to groundwater.

The predicted environmental concentrations ( $PEC_{gw}$ ) at 1 m depth for dicamba following 66 years (includes six years warm-up period) use on maize either at 160 g a.s./ha or at 200 g a.s./ha with 25% foliar interception, were less than 0.001  $\mu\text{g/L}$  in all scenarios using FOCUS-PELMO, FOCUS-PEARL and FOCUS MACRO models and a  $DT_{50}$  of 4.0 days.

The models predict that dicamba and its metabolite DCSA will not be found in groundwater at concentrations equal to or greater than 0.1 µg/L. Based on the assessment, the use of dicamba is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

**The maximum PEC<sub>GW</sub> values for active substances were below the trigger value of 0.1 µg/L if dicamba was applied every 3<sup>rd</sup> year.**

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

#### **Prosulfuron**

Predicted environmental concentrations in surface water (PEC<sub>sw</sub>) and sediment (PEC<sub>sed</sub>) were calculated for the use of prosulfuron as herbicide in maize in Europe in accordance with FOCUS guidelines. Models used for calculations were FOCUS STEPS 1-2 v 3.2, FOCUS SWASH v5.3 and EU agreed endpoints (EFSA Journal 2014a;12(9): 3815). The Step 4 was also performed – SWAN model and VFSmod were used. Mitigation measures were proposed.

Further for prosulfuron, a tiered approach was undertaken. The degradation and dissipation of prosulfuron was studied in soil under laboratory and field conditions, respectively. Both was considered in modelling and simulated separately as Tier 1 and Tier 2.

- In Tier 1 the geometric mean laboratory DegT<sub>50</sub> (20°C/Q<sub>10</sub> = 2.58, pF2) of 62.1 days was used in combination with the arithmetic mean sorption parameters as stated in the EU review of prosulfuron.
- In Tier 2 the geometric mean field DT<sub>50</sub> (20°C/Q<sub>10</sub> = 2.58, pF2) of 18.7 days was used in modelling in combination with geometric mean sorption parameter as a worst case.

Based on the recommended use rates of prosulfuron the maximum values for PEC<sub>sw</sub> and PEC<sub>sed</sub> for CGA150829, CGA159902, CGA300406, SYN542604, CGA349707 and CGA325025 have been calculated.

The results for PEC<sub>sw</sub> and PEC<sub>sed</sub> for the active substance and its metabolites were used for the ecotoxicological risk assessment.

#### **Nicosulfuron**

The PEC of nicosulfuron in surface water (PEC<sub>sw</sub> and PEC<sub>sed</sub>) has been assessed with the FOCUS surface water models FOCUS-STEPS 1-2 v3.2, FOCUS SWASH v5.3, (FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3), ECPA SWAN v5.0 and VFSmod), as well as the DT<sub>50</sub> water/sediment values established in the EU review. More recently an additional soil adsorption study was undertaken by Cheminova in which adsorption to a further 10 soils was studied. Syngenta have been given access to the study summary (Graham and Strachan, 2008). With this additional study and considering all adsorption values (n=14), the geometric mean K<sub>FOC</sub> is increased to 24.6 mL/g. Mitigation measures were proposed.

The PEC of nicosulfuron metabolites HMUD, AUSN, ADMP, UCSN and ASDM in surface water (PEC<sub>sw</sub> and PEC<sub>sed</sub>) has been assessed with the FOCUS surface water model STEPS 1-2, and the DT<sub>50</sub> water/sediment values and endpoints established in the EU review or dRR, Part B8, Section 8.3 – 8.6. Based on the recommended use rates of nicosulfuron the maximum values for PEC<sub>sw</sub> and PEC<sub>sed</sub> for HMUD, AUSN, ADMP, UCSN and ASDM have been calculated.

The results for PEC<sub>sw</sub> and PEC<sub>sed</sub> for the active substance and its metabolites were used for the ecotoxicological risk assessment.



## Dicamba

The PEC of dicamba in surface water ( $PEC_{sw}$  and  $PEC_{sed}$ ) has been assessed with the FOCUS surface water model STEPS 1-2 and the  $DT_{50}$  total system values established in the EU review. The modelled use rate considered a single application of either 160 g/ha or 200 g/ha dicamba to maize in Northern and Southern Europe in spring season. The maximum (Step 2) values for  $PEC_{sw}$  and  $PEC_{sed}$  have been calculated according to FOCUS Step 1 and 2 for dicamba.

The PEC of Dicamba metabolite DCSA (NOA414746) in surface water ( $PEC_{sw}$  and  $PEC_{sed}$ ) has been assessed with the FOCUS STEPS 1-2 model and the  $DT_{50}$  total system values established in the EU review or dRR, Part B8, Section 8.3 – 8.6. Based on the recommended use rates of dicamba the maximum values for  $PEC_{sw}$  and  $PEC_{sed}$  for DCSA (NOA414746) has been calculated.

The results for  $PEC_{sw}$  and  $PEC_{sed}$  for the active substance and its metabolites were used for the ecotoxicological risk assessment.

## A18385B

The  $PEC_{sw}$  for A18385B considering the drift was also submitted. The mitigation measures were taken into consideration.

### 3.7.4 Predicted environmental concentrations in air ( $PEC_{air}$ )

#### Prosulfuron

The fate and behaviour of prosulfuron in air is considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of prosulfuron (Prosulfuron, EFSA Journal 2014; 12(9): 3815).

The vapour pressure at 25°C of the active substance prosulfuron is  $< 10^{-5}$  Pa. Hence the active substance prosulfuron is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance prosulfuron due to volatilization with subsequent deposition should not be considered.

#### Nicosulfuron

The fate and behaviour of nicosulfuron in air are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of nicosulfuron (Nicosulfuron, EFSA Scientific Report (2007) 120, 1-91).

The vapour pressure at 20°C of the active substance nicosulfuron is  $< 10^{-5}$  Pa. Hence the active substance nicosulfuron is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance nicosulfuron due to volatilization with subsequent deposition should not be considered.

## Dicamba

The fate and behaviour of dicamba in air are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of dicamba (Dicamba, EFSA Journal 2011;9(1):1965).

Although the estimated half-life in air is greater than 2 days, dicamba is unlikely to be subject to long range aerial transport in any environmentally relevant amounts. It must be kept in mind that the  $DT_{50}$  in air of 2 days is only used as an initial screen or trigger to determine whether a pesticide has a *potential* for long range transport. The high water solubility of dicamba indicates that particles will be more efficiently scavenged by rain and will travel much shorter distances. The amount of dicamba potentially transferred into the air is estimated to be very low (based on experimentally derived data) and subsequent transport and deposition (and degradation) in air, which must be expected to result in a broad diffusion over wide areas, will lead to further 'dilution' and reduction in concentrations. These facts combined with the experimentally derived degradation data available for soil and water/sediment environments indicate that

any amounts of dicamba undergoing long-range transport and subsequent deposition at distances from the source will undergo subsequent breakdown. An accumulation in any relevant amounts is not expected and must be considered as highly unlikely. Moreover, no unacceptable ecotoxicological impact of dicamba in areas directly adjacent to or in treated areas has been demonstrated in appropriate risk assessments.

For these reasons, although dicamba may have the potential for long-range transport through the atmosphere, no environmentally relevant impact or risk is considered to be realistically likely to occur and the presented data are deemed sufficient for this Annex point in the registration of A18385B.

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

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

The acute and long-term risks of A18385B to birds and mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with prosulfuron, nicosulfuron and dicamba, and maximum residues occurring on food items following applications according to the proposed use pattern. The risk to birds and mammals from exposure *via* drinking water has also been assessed.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk for prosulfuron, nicosulfuron, dicamba, and the mixture toxicity of the three substances indicating that the risk to birds and mammals is acceptable following use of A18385B according to the proposed use pattern. Acceptable risk to birds from exposure *via* drinking water was also shown.

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

##### **Prosulfuron + Nicosulfuron + Dicamba and A18385B**

The PEC/RAC ratios, using worst-case PEC<sub>SW</sub> values for A18385B, are less than the trigger value of 1, for all aquatic organisms, with the exception of aquatic plants exposed to prosulfuron, nicosulfuron and A18385B. A refined risk assessment is conducted for aquatic plants exposed to prosulfuron, nicosulfuron and A18385B taking into account appropriate mitigation measures.

The FOCUS Step 4 PEC/RAC ratios were calculated based on FOCUS Step 4 PEC<sub>SW</sub> considering reduced exposure of surface water bodies as an additional refinement option.

Additionally, the mixture toxicity assessment was conducted.

Overall, the risk to aquatic plants is acceptable following the proposed use pattern of 400 or 500 g A18385B/ha implementing drift and run-off mitigation.

To protect aquatic organisms respect an unsprayed, vegetated buffer zone of 5 m to surface water bodies.

#### **3.8.3 Effects on bees**

The risk of A18385B to honey-bees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with A18385B, prosulfuron, nicosulfuron and dicamba, and the maximum single application rates.

All the hazard quotients are less than 50, indicating that the risk to bees is acceptable following use of A18385B according to the proposed use pattern.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees): The Applicant should provide chronic test on bees and evaluation of effects on honey bee development with formulated product. The chronic studies were not performed, therefore, for Poland, the deficiencies need to be fulfilled by the entry into force of the revised EFSA bee guideline.

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

At Tier I, the in-field HQ values were below the trigger value for the worst case use scenarios (1 x 400 and 1 x 500 g A18385B/ha in maize) indicating the need for further refinement. The off-field HQ values

were below the trigger value for all proposed uses indicating that the risk to in-field non-target arthropods is acceptable following the use of A18385B according to the proposed use pattern.

The Tier II, extended laboratory studies showed acceptable foliar in-field and off-field effects from foliar applications of A18385B for *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Chrysoperla carnea* and *Aleochara bilineata* for the worst case use scenarios (1 x 400 and 1 x 500 g A18385B/ha in maize). The risk to non-target arthropods is therefore acceptable following use of A18385B according to the proposed use pattern.

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

The acute and long-term risk of A18385B to earthworms was assessed from acute and long-term toxicity exposure ratios (TERs) between the selected toxicity endpoints for A18385B, prosulfuron, nicosulfuron, dicamba and relevant metabolites, and the maximum PEC<sub>soil</sub> values. All acute and chronic TER values are greater than the Regulation (EU) 546/2011 triggers of 10 and 5, respectively, indicating that the risk to earthworms is acceptable following use of A18385B according to the proposed use pattern.

The risk of A18385B to other non-target soil macro-organisms, as represented by *Collembola* and *Hypoaspis*, was assessed from long-term toxicity exposure ratios (TERs) between the selected no-effect concentrations, derived from laboratory tests on relevant metabolites, and the maximum PEC<sub>soil</sub>. The TER<sub>LT</sub> values are all greater than the recommended trigger value of 5, indicating that the risk to soil macro-organisms, as represented by *Collembola* and *Hypoaspis*, is acceptable following use of A18385B according to the proposed use pattern.

The risk of A18385B, prosulfuron, nicosulfuron, dicamba and relevant metabolites to soil micro-organisms was evaluated by comparison of the maximum concentrations with effects  $\leq 25\%$  derived from laboratory tests, with maximum PEC<sub>soil</sub>.

All the effect levels exceeded the relevant PEC<sub>soil</sub> values, indicating that the risk to soil micro-organisms is acceptable following the use of A18385B according to the proposed use pattern.

### **3.8.6 Effects on non-target terrestrial plants**

The risk of A18385B to non-target terrestrial plants was assessed from toxicity exposure ratios (TERs) using the formulation toxicity data from Tier II studies using a calculated HC<sub>5</sub>, and the maximum off-field predicted environmental residues (PERs). Higher tier field studies have been used to further refine the risk assessment.

Based on the most sensitive ER<sub>50</sub> of the higher tier field studies, the risk to non-target terrestrial plants in off-crop areas is acceptable following use of A18385B according to the proposed use pattern, provided the following mitigation is implemented:

#### 1 x 400 g A18385B/ha:

- 75% drift reduction or
- 5 m buffer

#### 1 x 500 g A18385B/ha:

- 90% drift reduction mitigation or
- 5m buffer

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

Tests on other non-target species are not required.

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

### **Prosulfuron metabolites**

The 3 metabolites CGA349707, CGA159902, CGA150829 are predicted to occur in groundwater at concentrations above 0.1 µg/L, whereas CGA300406, CGA325025, SYN547308 and SYN542604 showed concentrations below 0.1 µg/L (see Section B8). However, assessment of the relevance of all metabolites according to the stepwise procedure of the EC guidance document (SANCO/221/2000 –rev.10) is presented in Section B10.

The outcome of the assessment shows that all metabolites can be considered to be non-relevant in the context of the criteria outlined in the “Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated Under Council Directive 91/414/EEC. (SANCO/221/2000-rev.10; 25 February 2003).

#### **Nicosulfuron metabolites**

The metabolite ADMP is predicted to occur in groundwater <0.001 µg/L, the metabolite MU-466 and the metabolite HMUD >0.1 µg/L but <0.75 µg/L. The metabolites AUSN, UCSN and ASDM are predicted to occur in groundwater at concentrations >0.75 µg/L but <10 µg/L. The assessment of the relevance of metabolites MU-466, HMUD, AUSN, UCSN and ASDM according to the stepwise procedure of the EC guidance document (SANCO/221/2000 –rev.10) is presented in Section B10.

The outcome of the assessment shows that all metabolites can be considered to be non-relevant in the context of the criteria outlined in the “Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated Under Council Directive 91/414/EEC. (SANCO/221/2000-rev.10; 25 February 2003).

#### **Dicamba metabolites**

DCSA (NOA414746) will not be measured in ground water at concentrations equal to, or greater than 0.1 µg/L. Therefore, further assessment of the potential relevance of DCSA (NOA414746) is not required.

## Appendix 1 Copy of the product label

### Uwagi do etykiety:

Fizykochemia – dopisano informację o możliwości stosowania środka w mieszaninie z adjuwantem z grupy adjuwantów olejowych – ~~Adigor 440 EC~~.

Toksykologia – dodano zwrot P264.

Pozostałości – brak uwag.

Los i zachowanie w środowisku – dodano zwrot P501.

Ekotoksykologia – wprowadzono strefy ochronne, ~~zmieniono strefę ochronną dla organizmów wodnych~~.

Skuteczność działania – zmieniono treść etykiety w zakresie „Działanie na chwasty” oraz „Stosowanie środka”. W zakresie „Stosowanie środka” dodano zapis: „i unikać aplikacji środka w warunkach niekorzystnych dla roślin uprawnych.” Dodano zapis: „Środek w dawce 0,5 kg/ha stosować przy wyższym nasileniu chwastów, w tym psianki czarnej lub na chwasty w wyższym stadium rozwojowym.”

Posiadacz zezwolenia:

Syngenta Polska Sp. z o.o., ul. Szamocka 8, 01-748 Warszawa, Rzeczpospolita Polska.  
Tel.: (22) 326 06 01. Fax.: (22) 326 06 99.

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka:....



## Spandis 54 WG

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

dikamba (związek z grupy pochodnych kwasu benzoowego) – 400 g/kg (40%),  
nikosulfuron (związek z grupy pochodnych sulfonilomocznika) – 100 g/kg (10%),  
prosulfuron (związek z grupy pochodnych sulfonilomocznika) – 40 g/kg (4%).

**Zezwolenie MRiRW nr R - /2020 z dnia . .2020 r.,**

 	
<b>Uwaga</b>	
H319 H410	Działa drażniąco na oczy. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P264 P280 P305 + P351 + P338	Dokładnie umyć skórę po użyciu. Stosować rękawice ochronne/odzież ochronna/ochronę oczu/ochronę twarzy. W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P337 + P313	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P391 P501	Zebrać wyciek. Zawartość i pojemnik usuwać zgodnie z lokalnymi przepisami.

## OPIS DZIAŁANIA

HERBICYD w formie granul do sporządzania zawiesiny wodnej, stosowany nalistnie, przeznaczony do powschodowego zwalczania chwastów jednoliściennych oraz chwastów dwuliściennych w uprawie kukurydzy. Środek przeznaczony do stosowania przy użyciu opryskiwaczy polowych.

Spandis 54 WG zawiera w swoim składzie dwie substancje czynne.

Dikamba działa jako antagonist a auksyny i wiąże się konkurencyjnie z receptorami kwasu indolooctowego (IAA), prowadząc w ten sposób do zwiększonego stężenia IAA w tkankach merystematycznych, co inicjuje łańcuch zdarzeń deregulujących wzrost, wydłużanie i różnicowanie komórek roślinnych. Objawy uszkodzenia roślin typowe dla auksyn syntetycznych to: skręcanie się i zawijanie pędów i łodyg liści (epinastyka), obrzęki pędów, wydłużenia i deformacje liści. Po tych objawach następuje chloroza w punktach wegetatywnych, karłowacenie, więdnienie i martwica. Pierwsze widoczne objawy pojawiają się u gatunków wrażliwych od 2 dni do kilku tygodni po aplikacji, w zależności od pogody. Najszybsze objawy występują podczas intensywnego wzrostu i podziału komórek. Dicamba należy do grupy HRAC O syntetycznych auksyn.

Nikosulfuron należy do grupy herbicydów sulfonilomocznikowych. Jest selektywną substancją o działaniu układowym szybko przemieszczającą się w roślinie. Głównie jest pobierany przez liście hamując ich wzrost i rozwój. Według klasyfikacji HRAC nikosulfuron należy do grupy B jako Inhibitor biosyntezy aminokwasów (inhibitor funkcjonowania syntazy acetolaktanowej). Charakterystycznymi objawami po zastosowaniu środka są:

- bielenie roślin,
- zahamowanie wzrostu, zwłaszcza merystemów korzeniowych, które obserwuje się już w kilka godzin po zastosowaniu,
- podłużne chlorozy liści - różowe bądź czerwone zabarwienie nerwów,
- obumieranie tkanek w okolicy merystemów i w efekcie zamieranie całych roślin; objawy widoczne są dopiero po kilkunastu dniach (czasami w przypadku niekorzystnych warunków pogodowych po 3 tygodniach).

Prosulfuron hamuje enzym syntazy acetylomleczanowej (enzym ALS), który katalizuje pierwszą fazę biosyntezy aminokwasów rozgałęzionych. Prosulfuron należy do grupy HRAC B, inhibitorów biosyntezy aminokwasów (inhibitor funkcjonowania syntazy acetolaktanowej). Brak niezbędnych aminokwasów zmniejsza podział komórkowy; rośliny wrażliwe przestają rosnąć kilka godzin po zabiegu, jednak objawy działania takie jak żółknięcie roślin, czerwone przebarwienia, pojawiają się od kilku dni do dwóch tygodni po zabiegu. Kompletnie zamieranie roślin ma miejsce jeden do dwóch tygodni później, zależnie od gatunku chwastu oraz czynników środowiska takich jak temperatura i wilgotność.

## DZIAŁANIE NA CHWASTY

### Chwasty wrażliwe:

Szarłat szorstki, tasznik pospolity, komosa biała, żóltlica drobnokwiatowa, jasnota purpurowa, maruna bezwonna, rdestówka powojowata, rdest kolankowaty, gwiazdnica pospolita, tobołki polne, ~~wyeczyniee polny~~, chwastnica jednostronna, ~~perz właściwy~~, przetacznik perski, fiołek polny, bodziszek drobny, przytulia czepna, rumianek pospolity, rumian polny

### Chwasty średniowrażliwe:

~~Rdest kolankowaty~~-perz właściwy, psianka czarna

### Chwasty odporne:

Powój polny

## STOSOWANIE ŚRODKA

### Kukurydza

Maksymalna dawka dla jednorazowego zastosowania: 0,5 kg/ha

Spandis 54 WG 0,5 kg/ha + Adjuvant z grupy adjuwantów olejowych - ~~Adigor 440 EC~~ 1,0 - 1,5 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,4 kg/ha

Spandis 54 WG 0,4 kg/ha + Adjuvant z grupy adjuwantów olejowych – Adigor 440 EC 1,0 - 1,5 l/ha

Środek w dawce 0,5 kg/ha stosować przy wyższym nasileniu chwastów, w tym psianki czarnej lub na chwasty w wyższym stadium rozwojowym.

Środek należy stosować raz na trzy lata na tym samym polu w maksymalnej dawce 20 g substancji czynnej prosulfuron na hektar.

Termin stosowania: zabieg można wykonać po wschodach kukurydzy (od fazy 2 liści do fazy 8 liści rośliny uprawnej, BBCH (12-18).

Zalecana ilość wody: 200-150-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Środek może powodować przejściowe deformacje, przebarwienia, obniżenie wigoru oraz trwały spadek wzrostu roślin, bez wpływu na plonowanie rośliny. Aby takich skutków uniknąć, środek należy stosować na aktywnie rosnące, suche uprawy i unikać aplikacji środka w warunkach niekorzystnych dla roślin uprawnych.

## **NASTĘPSTWO ROŚLIN**

W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem Spandis 54 WG (w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na polu można uprawiać kukurydzę. Po wykonaniu głębokiej orki oprócz kukurydzy można uprawiać także groch, rzepak, pszenicę ozimą i żyto po upływie 14 dni od zastosowania. Po zbiorze kukurydzy uprawianej w normalnych warunkach wegetacji, odchwaszczanej środkiem Spandis 54 WG do 1 lipca oraz po wykonaniu głębokiej orki można wysiewać wszystkie rośliny uprawne. W przypadku uprawy roślin wrażliwych tj. buraka, strączkowych, rzepaku ozimego, słonecznika i warzyw oraz wcześniej sianych zbóż ozimych możliwe jest wystąpienie uszkodzeń.

W skrajnie niekorzystnych warunkach (gleby piaszczyste, gleby łatwo przesychające, gleby o niskim pH [ $<6.0$ ], gleby o wysokiej zawartości substancji organicznej [ $>4.0\%$ ], niskiej aktywności biologicznej, wyjątkowo niskich temperaturach w okresie zimowym, wyjątkowo niskiej wilgotności gleby latem i/lub jesienią i/lub zimą, nakładania się powierzchni opryskanej preparatem, gleby nadmiernie ugniecionej) mogą wystąpić tymczasowe wybielenia, zahamowanie wzrostu, zmniejszenie obsady w roślinach wrażliwych (buraki, strączkowe, słonecznik i warzywa). Dlatego też uprawa w/w roślin jako roślin następczych nie jest zalecana, gdy pH gleby jest znacznie poniżej 6.0 lub jeśli po zastosowaniu środka w poprzednim sezonie, wystąpił długotrwały okres posuchy. Głęboka orka po uprawie kukurydzy i pH gleby ponad 6.0 znacząco zmniejszają ryzyko uszkodzeń tych roślin.

## **ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA**

Okres od zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):  
nie wymagany

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta: nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

Podczas stosowania środka nie dopuścić do:

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

## **SPORZĄDZANIE CIECZY UŻYTKOWEJ**



Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.  
Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem) i uzupełnić wodą do potrzebnej ilości.

Opryskiwać z włączonym mieszadłem.

Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz w zbiorniku mechanicznie wymieszać.

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową.

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

#### *POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ, ODPADAMI I MYCIE APARATURY*

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

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

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej.

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

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

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

Unikać zanieczyszczenia skóry.

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

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

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie nieopryskiwanej, zadarnionej strefy ochronnej o szerokości **5 m** od zbiorników i cieków wodnych:

~~5 m lub~~

~~1 m z jednoczesnym użyciem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.~~

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od terenów nieużytkownych rolniczo lub strefy ochronnej o szerokości 1 m od terenów nieużytkownych rolniczo z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90% dla dawki 0,5 kg środka/ha lub 75% dla dawki 0,4 kg środka/ha.

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



Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze nieprzekraczającej zakresu 0 - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów. Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych. Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

### **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

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

W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć.

W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności – 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

## **Appendix 2 Letter of Access**

Required letters of access are enclosed with the covering letter.

## **Appendix 3 Lists of data considered for national authorization**

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

Please refer to the reference list.

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

Please refer to the reference list.