FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: A18385B

Product name: Spandis 54 WG

Chemical active substances:

Prosulfuron: 40 g/kg
Dicamba: 400 g/kg
Nicosulfuron: 100 g/kg

Central Zone

Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Syngenta

Submission date: 26/11/2020

MS Finalisation date: 11/07/2022

Version history

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

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- Following expiry of any period of exclusive use, by offering, in certain jurisdictions, mandatory compensation,

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Applicants wishing to avail of information in this registration report should seek advice from the regulatory authority to which the application is made concerning the requirements in their country.

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

Comments of zRMS:	Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. The parts of the text amended or added by the zRMS evaluator are highlighted in grey and the parts struck off are ~~visibly marked~~ with the grey front.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

zRMS

The submitted efficacy data (reports from field trials) fulfil requirements and conditions determined in the EPPO guidelines, the Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products. The reports and data were submitted to support the evaluation for the authorization of A18385B in Poland (NE EPPO climatic zone).

A18385B The product contains 40 g/kg of prosulfuron, 400 g/kg of dicamba, 100 g/kg of nicosulfuron and is formulated as a water dispersible granule (WG). It is used as herbicide in maize for the control of a wide range of weeds at dose rates of 0,4 kg/ha and 0,5 kg/ha (plus oil-based adjuvant 1,0 L/ha or 1,5 L/ha, spray volume applied on the crop was 150 – 400 l/ha) as post – emergence one application every third year.

The applicant submitted 35 reports showing the results in research into product efficacy carried out in Poland, the Czech Republic and Germany from 2012 to 2015, on different cultivars of *Zea mays* against: grass and broad-leaved weeds to supports the registration of A18385B in Poland. The Applicant has presented document of climate comparability between the region of Wielkopolskie and Hannover, Luneburg, Mecklenburg-Vorpommern, Sachsen-Anhalt, Unterfranken to indicate that data from DE and CZ (the Maritime EPPO climatic zone) are relevant for Poland.

Weed species are classified as:

susceptible (S) –	85%
moderately susceptible (MS) -	70-84,9%
moderately tolerant (MT)	60 -69,9%
tolerant (T)	< 60%

50 – 60 days after application the following target weed species were categorized as:

- susceptible (S):
for dose rate 0,4 kg/ha: ECHCG, AMARE, CAPBP, CHEAL, GALAP, GASPA, GERPU, LAMPU, MATCH, MATIN, MATMA, POLCO, POLLA, STEME, THLAR, VERPE, VIOAR
for dose rate 0,5 kg/ha: ECHCG, AMARE, CAPBP, CHEAL, GALAP, GASPA, GERPU, LAMPU, MATCH, MATIN, MATMA, POLCO, POLLA, STEME, THLAR, VERPE, VIOAR

- moderately susceptible (MS):
for dose rate 0,4 kg/ha: AGRRE
for dose rate 0,5 kg/ha: AGRRE, SOLNI

- moderately tolerant (MT):
for dose rate 0,4 kg/ha: CONAR, SOLNI
for dose rate 0,5 kg/ha: CONAR

CONAR showed week (moderately tolerant) susceptibility on A18385B at dose rate 0,4 kg/ha and 0,5 kg/ha. There is a need to make an appropriate label statement.

What is more, A18385B showed less consistent results 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.

Results from efficacy trials demonstrate that A18385B at the dose rate 0,4 kg/ha and 0,5 kg/ha (plus oil-based adjuvant 1,0 L/ha or 1,5 L/ha) is a good alternative to standard herbicides for the control of some weeds in maize in post-emergency application with maximum one application in one season every third year.

The applicant presented strategy of resistance management recommended by HRAC. Nevertheless in case any new information which would change the resistance risk analysis regulatory authorities should be informed about it.

Adverse effects might appeared occasionally after the product application. They might be transient or long lasting and they should not cause reductions in yield. Nevertheless information on applying the product on actively growing dry crops and avoid applications in any crop stress situation should be placed on the label.
The product A18385B is to be expected no negative effect on the quality of plants or plant products and transformation processes.
In relation to succeeding crops safety, the only safe cultivation at the early sowing is maize. After deep soil cultivation (ploughing) peas, oilseed rape, winter wheat and rye grass may be sown as replacement crops beyond 14 days after application. What is more for oilseed rape, winter wheat and rye grass sown in the early autumn, a deep soil cultivation is recommended to secure the crop safety.
Use of A18385B should be safe for non-target terrestrial plants in off-crop areas if the following mitigation is implemented: 5m buffer or 1 m buffer with using 90% drift-reducing nozzles.
The cleaning procedure of the tank after using A18385B presented by the Applicant is expected to be sufficient cleaning procedure.

According to the above, the plant protection product A18385B is recommended to be approved to use according to the table of intended uses for A18385B (Table 3.1- 1). The evaluation was carried out in accordance with the Uniform Principles.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11			12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp 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, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha nicosulfuron a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha prosulfuron a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha dicamba a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)																
1	PL	Maize	F	Annual/ perennial broad leave weeds and grasses	Foliar spray	BBCH 12-18	1 (1 appl. every 3rd year)	N/A	a) 0.5 b) 0.5	a) 20 b) 20	a) 50 b) 50	a) 200 b) 200	~~200~~150-400	n.s.	tank-mixed oil-based adjuvant needed (e.g Adigor@ 1.0-1.5L/ha)	A
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) 0.4 b) 0.4	a) 16 b) 16	a) 40 b) 40	a) 160 b) 160	~~200~~150-400	n.s.	proportional mitigation; tank-mixed oil-based adjuvant needed (e.g Adigor@ 1.0-1.5L/ha)	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** 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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy of the plant protection product A18385B containing the active substances nicosulfuron, prosulfuron and dicamba.

Relevant review information (or a reference to where such information can be found) is provided by the SANCO/EFSA reports for nicosulfuron (SANCO/3780/07), prosulfuron (SANCO/3055/99) and dicamba (SANCO/829/08). Specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the member state prior to granting an authorisation is provided by the Annex I Inclusion Directives for nicosulfuron (2008/40/EC), prosulfuron (2002/48/EC) and dicamba (2008/69/EC).

This dossier is compiled according to Commission Regulation 1107/2009 dated 21.10.2009 and guideline SANCO/6895/2009 rev 1 dated 02.10.2009 (Guidance on the presentation and evaluation of dossiers) and follows the data requirements of Commission Regulation (EU) No 545/2011 dated 10 June 2011. It is based on the results of field trials carried out between 2012 and 2015 for the assessment of the biological performance. This document summarises the information related to the efficacy and crop safety of the plant protection product A18385B. The trials were carried out in relevant countries in the North-East and Maritime EPPO zones.

A18385B (synonym CHA 7980) is a 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. For details, please refer to the national registration databases.

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.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	**KCP 6 / 01 Biological Assessment Dossier A18385B** Syngenta File No. VV-870122

Description of active substances

A18385B contains the active ingredients (AI) nicosulfuron, prosulfuron and dicamba. It is formulated as a water dispersible granule (WG) and contains 100 g/kg of nicosulfuron, 40 g/kg of prosulfuron and 400 g/kg of dicamba. Information on the detailed composition of A18385B can be found in the confidential dossier of this submission (Registration Report - Part C).

Mode of action

Table 3.2-1: Details of the active substances

Active substance	nicosulfuron	prosulfuron	dicamba
Concentration	100 g/kg	40 g/kg	400 g/kg
Chemical group	Sulfonylureas	Sulfonylureas	Benzoic acids
Mode of action	Absorbed by roots, shoots and foliage and translocated. Inhibits the acetolactate synthase enzyme (ALS) **(HRAC group B or 2)** Stops cell division and plant growth	Absorbed by roots, shoots and foliage and translocated. Inhibits the acetolactate synthase enzyme (ALS) **(HRAC group B or 2)** Stops cell division and plant growth	Absorbed by roots, shoots and foliage and translocated. Acts as auxin agonist and binds competitively to receptors of indoleacetic acid (IAA) **(HRAC group O or 4)** Deregulates plant cell growth, elongation and differentiation
Plant translocation	Systemic	Systemic	Systemic
Biological action	Foliar/residual	Foliar/residual	Foliar/ non-residual

Information on nicosulfuron

The active ingredient nicosulfuron is a well-known herbicide which has been widely used throughout the world for more than 20 years. In Europe it is authorised in almost all countries where maize is grown under a number of different trade names, either as a straight nicosulfuron product or in combination with other maize selective active ingredients. For details, please refer to the national registration databases. Major examples are Nisshin, Elumis, Fornet and Principal.

A short description of relevant properties of nicosulfuron is given in **Table 3.2-1**. For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Uptake, Mode of action

Nicosulfuron inhibits 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 treatment. Injury symptoms appear several days after treatment and the complete death happens one or two weeks later.

Information on prosulfuron

The active ingredient prosulfuron is a well-known herbicide which has been widely used throughout the world for about 15 years. In Europe it is authorised in almost all countries where maize is grown under a number of different trade names, either as a straight prosulfuron product (Peak) or in combination with other maize selective active ingredients (Casper). For details, please refer to the national registration databases.

A short description of relevant properties of prosulfuron is given in in **Table 3.2-1**. For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Uptake, Mode of action

Prosulfuron inhibits 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 treatment. Injury symptoms appear several days after treatment and the complete death happens one or two weeks later.

Information on dicamba

The active ingredient dicamba is a well-known herbicide which has been widely used throughout the world in many monocotyledonous crops for more than 30 years. The use in maize is authorised in almost all European countries where maize is grown under a number of different trade names, either as a straight dicamba product or in combination with other maize selective active ingredients. For details, please refer to the national registration databases. Major examples in maize are: Banvel 4S, Mais-Banvel 75 WG, Casper and Cambio.

A short description of relevant properties of dicamba is given in in **Table 3.2-1**. For further physico-chemical properties, please refer to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Uptake, Mode of action

Dicamba acts as auxin agonist and binds competitively to receptors of indoleacetic acid (IAA), thus leading to IAA increased concentration in meristematic tissues, which initiates a chain of events that deregulate plant cell growth, elongation and differentiation. Symptoms of plant damage typical for synthetic auxins are: twisting and curling of shoots and leaf stalks (epinasty), shoot swellings, elongations and leaf deformations. These symptoms are followed by chlorosis at vegetative points, stunting, wilting and necrosis. First visible symptoms develop in sensitive species from 2 days to several weeks after application, depending on the weather and plant growth stage.

Description of the plant protection product

The detailed composition of A18385B can be found in the confidential dossier of this submission (Registration Report - Part C).

Spandis (A18385B) contains the active ingredients (AI) nicosulfuron, prosulfuron and dicamba. It is formulated as a water dispersible granule (WG) and contains 100 g/kg of nicosulfuron, 40 g/kg of prosulfuron and 400 g/kg of dicamba.

In maize, the proposed maximum rate of A18385B is 0.5 litre per hectare (l/ha) with a maximum of one application per season, which will deliver 50 g ncoslufuron, 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.

Simplified table of currently registered uses are prsented in **Table 3.2-2**

Further details are in the table "All intended uses" in Part B - Section 0.

Table 3.2-2: Simplified table of currently registered uses and requested uses for the product code

USES		Member State (and major minor status)	Registration Number of the existing registration	Currently registered uses	Requested/ registered uses	Comments/other relevant details on the GAPs
Crop	Target(s)					
Maize	grass and broadleaved weeds	Austria	3857/0	400 g/kg dicamba 100 g/kg nicosulfuron 40 g/kg prosulfuron	0.4 kg/ha	-
		Belgium	10650P/B		0.4 kg/ha	-
		Czech Republic	5234-0		0.4-0.5 kg/ha	-
		United Kingdom	19276		0.4 kg/ha	-
		Hungary	1822			-
		Netherlands	15345		0.4 kg/ha	-
		Poland	-		-	-
		Romania	318PC			-
		Slovenia	U34330-241/14/17		0.4-0.5 kg/ha	-
		Bulgaria	n/a		-	Expired
		Italy	17097		0.4-0.5 kg/ha	-
		Portugal	AV0982		0.4-0.5 kg/ha	-
		Spain	ES-00314		0.4-0.5 kg/ha	-
		Croatia	UP/I-320-20/14-01/550		0.4-0.5 kg/ha	-
		Serbia	321-01-879/2014-11		0.4-0.5 kg/ha	-

Further details are in the table "All intended uses" in Part B - Section 0.

Description of the target pests

Table 3.2-3: Glossary of pests mentioned in the dossier

EPPO code	Scientific name	Common name*
ALOMY	*Alopecurus myosuroides*	blackgrass
AMASS	*Amaranthus species*	amaranthus
CAPBP	*Capsella bursa-pastoris*	shepherd's-purse
CHEAL	*Chenopodium album*	fat hen
CONAR	*Convolvulus arvensis*	field bindweed
ECHCG	*Echinochloa crus-galli*	cockspur
AGRRE	*Elymus repens*	quackgrass
POLCO	*Fallopia convolvulus*	wild buckwheat
GASPA	*Galinsoga parviflora*	smallflower galinsoga
GALAP	*Galium aperine*	-
GERPU	*Geranium pusillum*	smallflower geranium
LAMPU	*Lamium purpureum*	red deadnettle
MATSS	*Matricaria species*	chamomile
POLAV	*Polygonum aviculare*	prostrate knotweed
POLLA	*Polygonum lapathifolium*	pale smartweed
SOLNI	*Solanum nigrum*	black nightshade
STEME	*Stellaria media*	common chickweed
THLAR	*Thlaspi arvense*	field pennycress
VERPE	*Veronica persica*	persian speedwell
VIOSS	*Viola species*	violet

* optional

Table 3.2-4: Major / minor status of intended uses (for all cMS and zRMS)

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Maize	PL	-	grass weeds	x	
			broadleaved weeds	x	

Compliance with the Uniform Principles

Trials in this dossier were carried out by Syngenta organisations, contractor companies and official research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). All the trials were conducted according to GEP and EPPO-guidelines/-principles and the specifications of the trial plan. All assessments and applications were done according to instructions of the protocol unless otherwise specified. No deviations were recorded.

Information on trials submitted (3.1 Efficacy data)

A total of 53 efficacy field trials are presented. Trials were carried out between 2012 and 2015 seasons in Germany, Czech Republic and Poland representing the Maritime and North-East EPPO zone.

Table 3.2-5: Presentation of trials (efficacy trials, preliminary trials...)

Crop*	Targets*	Country	Years	Type of trial**	Number of trials		GEP or official***
					Maritime EPPO zone	North-East EPPO zone	
Maize varieties	Broadleaved and grass weeds	Germany	2012, 2013	P, MED, E	14	-	GEP
		Czech Republic	2012,-2014	P, MED, E	7	-	GEP
		Poland	2013-2015	P, MED, E	-	12	GEP
Total					**33**		**GEP**

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).
** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.
*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

All trials were set up in the most important regions for the production of maize in Europe due to ideal pedo-climatic conditions for maize growing. For the referred uses against broadleaved weeds, grass weeds claimed in this dossier, weeds' dynamics in countries where trials have been placed in the maize crop are considered to be fully representative. All trials carried out in each country, can be extrapolated to Poland belonging to the North-East agro-climatic zone. A statement of comparability is provide for the German trial locations with Poland in **Table 3.2-6**

The grouping and summarisation of trials presented in this dossier follow the EPPO climatic zones, as specified in EPPO guideline 1/241 (1) *Guidance on comparable climate.*

Table 3.2-6: Comparability beetween German trial locations and Wielkopolskie (PL)

Nr doświadczenia	Region 1	Region 2	Similarity for expert weight in % points	Similarity for effective weight in % points	Decription	Report No
DEMVZH9112013, DENOZH1602013	Wielkopolskie	Mecklenburg-Vorpommern	87.42	87.96	high similarity	1
DEOSZH3662012, DEOSZH3662013, DEOSZH3442013, DEESZH3212012	Wielkopolskie	Sachsen-Anhalt	87.71	88.13	high similarity	2
DEWEZH2352012	Wielkopolskie	Hannover	82.47	83.61	high similarity	4
PLvs PL	Wielkopolskie	Warminsko-Mazurskie	84.26	84.64	high similarity	6

Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Nicosulfuron products are the standards against grasses, either at 40 gai/ha on annuals or at 60 gai/ha on perennials.

Casper + adjuvant is the standard against both annual and perennial dicots. Further reference products included are Peak + adjuvant (on annual dicots) or Banvel (on perennial dicots). In a few countries these were replaced by Casper.

EPPO zone	T / S*	Trade name	Composition	Rates [L(kg)/ha]	N° of trials	Country (where used as standard)
Maritime	T*	A18385B (CHA 7980) & ADIGOR	nicosulfuron (100 g/kg)+prosulfuron (40 g/kg)+dicamba (400 g/kg) & emulsified fatty acid esters ( )	0.4/0.5 & 1.5	18/18	CZ, DE
	S	Milagro/ Samson 4 SC	nicosulfuron (40 g/L)	1/1.5	18/18	CZ, DE
		Peak & Trend 90	prosulfuron (750 g/kg) & Isodecyl alcohol ethoxylate (900 g/L)	0.02 & 0.1 %V/V	8/18	DE
		Casper & Trend 90	prosulfuron (50 g/kg)+dicamba (500 g/kg) & Isodecyl alcohol ethoxylate (900 g/L)	0.3 & 0.1 %V/V	18/18	CZ, DE
North-East	T	A18385B (CHA 7980) & ADIGOR	nicosulfuron (100 g/kg)+prosulfuron (40 g/kg)+dicamba (400 g/kg) & emulsified fatty acid esters ( )	0.4/0.5 & 1.5	12/12	PL
	S	Milagro	nicosulfuron (40 g/L)	1/1.5	5/12	PL
		Casper & Trend 90	prosulfuron (50 g/kg)+dicamba (500 g/kg) & Isodecyl alcohol ethoxylate (900 g/L)	0.3 & 0.1 %V/V	5/12	PL
		Columbus 51 WG & Trend 90	Mesotrione (118) + Nicosulfuron (39.6) + Rimsulfuron (9.8) & Sodecyl Alcohol Ethoxylate	0.33 KG/HA	6/12	PL

*) T = Test product, S = Reference product

Comments of zRMS:	This report summarizes the information concerning the efficacy of the plant protection product Spandis 54 WG (product code A18385B). The product contains 40 g/kg of prosulfuron, 400 g/kg of dicamba, 100 g/kg of nicosulfuron and is formulated as a water dispersible granule (WG). It is used as herbicide in maize. The reports and data were submitted to support of the evaluation of the A18385B product authorization in Poland. The active substance prosulfuron is included in the Annex to Commission Implementing Regulation (EU) No 540/2011 containing the active substances approved for use in plant protection products under Regulation (EC) No 1107/2009 with the expiration of approval on 31/07/2024. According to general provisions applying to all substances listed in the Annex to commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No1107/2009 of the European Parliament and of the Council as regards the list of approved active substances specific provisions of Regulation (EU) No 540/2011 were as follows: For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on prosulfuron including its addendum, and in particular Appendices I and II thereto, shall be taken into account. In that overall assessment Member States shall pay particular attention to: - the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;

	- the protection of consumers, taking into account exposure to metabolites of prosulfuron; - the risk to non-target terrestrial and aquatic plants. Conditions of use shall include risk mitigation measures, where appropriate. The active substance dicamba is included in the Annex to Commission Implementing Regulation (EU) No 540/2011 containing the active substances approved for use in plant protection products under Regulation (EC) No 1107/2009 with the expiration of approval on 31/12/2021. According to general provisions applying to all substances listed in the Annex to commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No1107/2009 of the European Parliament and of the Council as regards the list of approved active substances specific provisions of Regulation (EU) No 540/2011 were as follows: PART A: Only uses as herbicide may be authorised. PART B: For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of non-target plants. Conditions of use shall include adequate risk mitigation measures, where appropriate. The notifier shall submit confirmatory information as regards: (a) the identification and quantification of a group of soil transformation products formed in a soil incubation study; (b) the potential for long range transport through the atmosphere. The notifier shall submit this information to the Member States, the Commission and the Authority by 30 November 2013. The active substance nicosulfuron is included in the Annex to Commission Implementing Regulation (EU) No 540/2011 containing the active substances approved for use in plant protection products under Regulation (EC) No 1107/2009 with the expiration of approval on 31/12/2021. According to general provisions applying to all substances listed in the Annex to commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No1107/2009 of the European Parliament and of the Council as regards the list of approved active substances specific provisions of Regulation (EU) No 540/2011 were as follows: PART A: Only uses as herbicide may be authorised. PART B: For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on nicosulfuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: - the potential exposure of the aquatic environment to metabolite DUDN when is applied in regions with vulnerable soil conditions, - the protection of aquatic plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as buffer zones, - the protection of non-target plants and must ensure that the conditions of authorisation include, where appropriate, risk mitigation measures such as an in-field no-spray buffer zone, - the protection of groundwater and surface water under vulnerable soil and climatic conditions.

3.2.1 Preliminary tests (KCP 6.1)

Justification of the mixture

A18385B consists of the 3 active ingredients nicosulfuron, prosulfuron and dicamba. It is intended to provide almost complete weed control in maize. In this mixture nicosulfuron is required as the grass control component and the broad-leaved weeds control is predominantly based on prosulfuron and dicamba. Dicamba acts by foliar action without any residual activity and controls a broad spectrum of broad-leaved weeds, including some perennial weed species such as *Convolvulus arvensis*. Prosulfuron acts by foliar and root action and therefore provides the residual activity required for control throughout the season. The broad overlapping spectra of the 2 AIs, which have totally different modes of action, reduce the resistance risk and can be considered as an anti-resistance measure.

Nicosulfuron and prosulfuron are applied at around there recommended straight rates, since the full rates are required for grass control (nicosulfuron) and residual activity (nicosulfuron and prosulfuron). The rate of dicamba in A18385B is about 30 % lower than recommended for the straight products (200 g AI/ha vs. 288 g AI/ha). This reduction is possible due to the addition of prosulfuron. The performance of this mixture is confirmed by experiences with the already widely used ready-mix formulation of prosulfuron and dicamba applied at the same ratio (Casper 55 % WG) which is authorised for the control of broad-leaved weeds in maize in many European countries.

Preliminary work

The active ingredients in A18385B, nicosulfuron, prosulfuron and dicamba, are authorised and widely used for weed control in many countries inside and outside of Europe. It therefore is not deemed necessary to provide results from preliminary range finding tests. Therefore preliminary work focused on adjuvant studies.

Granule formulations generally do not contain built-in adjuvants. Therefore external adjuvants are used to optimize foliar absorption of the herbicide, resulting in an increased post-emergence efficacy. Thus it is intended to recommend the use of A18385B together with the most appropriate and commercially relevant adjuvant, which is available in the respective country. To demonstrate the favourable impact of the addition of an appropriate surfactant the results of 45 field tests carried out in 2012 (26) and 2013 (19) are presented below. The trials were established across the Central and Southern European Regulatory zones and across the climatic zones as defined by EPPO. In 3 further trials a comparison of different additives is performed.

For trials methodology, please refer to Section IIIA 6.1.3. Site and application details are located in Appendix 3 of the Biological Assessment Dossier.

In Figure 3.2-1 and Figure 3.2-2 summary box plot graphs of the results are presented. They show the level and variation of control from A18385B applied at 0.5 kg/ha on grasses (Figure 3.2-1) and broad-leaved weeds (Figure 3.2-2) with and without the addition of Adigor at 2 different rates (1.0 and 1.5 L/ha). The data is shown from all grasses and annual broad-leaved weed species which occurred in the trials. The trials were carried out in Bulgaria, Czech Republic, Great Britain, Greece, Hungary, Italy, Poland, Portugal, Serbia, Slovakia, Slovenia and Spain.

Figure 3.2-1: Effect of the addition of adjuvants on the grass control performance of A18385B

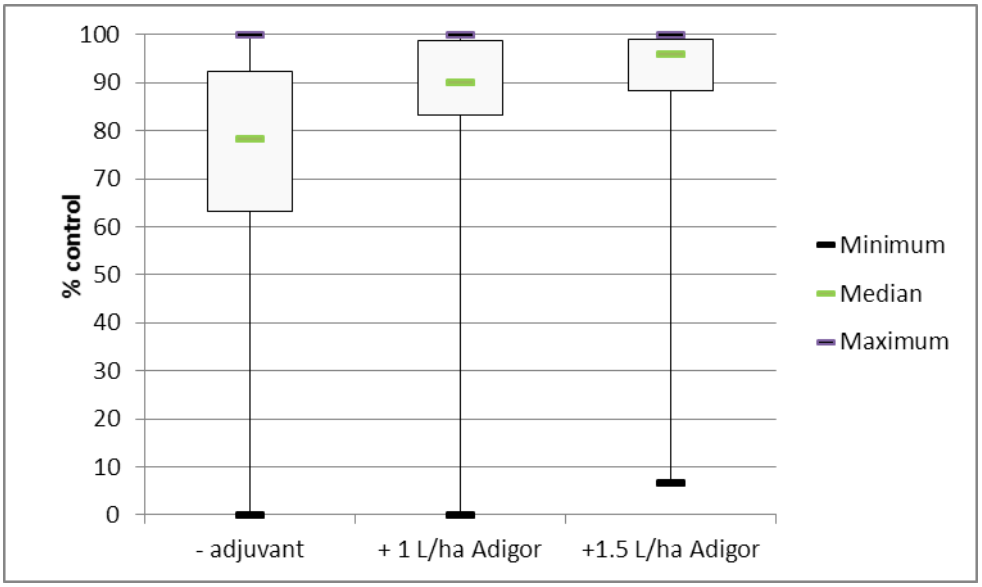
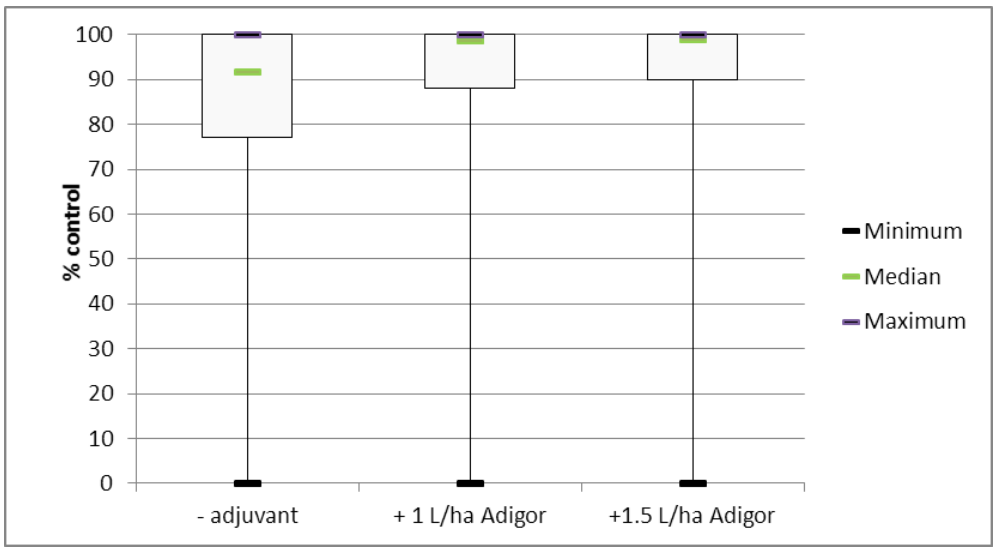


Figure 3.2-2: Effect of the addition of Adigor on the performance of A18385B for the control of broad-leaved weeds



The data shows that the addition of ADIGOR at either 1.0 or 1.5 L/ha improves the level and variation of weed control from A18385B. Differences between the rates are mainly visible on grasses; against broad-leaved weed species the differences between the rates of ADIGOR are lower.

Comparison of different adjuvants on the performance of A18385B (syn. CHA7980)

To compare the performance of A18385B with different adjuvants, A18385B was applied at 0.4 kg/ha without an adjuvant and in combination with different adjuvants. The results are based on 3 trials and 10 ratings of single weed species. Results presented in Table 3.2-8. Since not each adjuvant was tested in each trial, the results are grouped for direct comparisons based on identical trials and weed species.

Table 3.2-8: Comparison of the impact of the addition of different adjuvants on the performance of 0.4 kg/ha CHA7980 for weed control (% control across weed species)

DAA	oil based				NIS				
	# of results	+ Adigor	+ Codacide	+ Fortune	+ Biopower	+ Hyspray	+ Superspray	+ Trend 90	no Adjuvant
Mean - comparison set 1	*10*	*-*	*85*	*92*	*94*	*-*	*-*	*94*	*66*
Mean - comparison set 2	*7*	*95*	*89*	*95*	*92*	*-*	*-*	*92*	*72*
Mean - comparison set 3	*7*	*-*	*88*	*92*	*96*	*-*	*86*	*97*	*76*
Mean - comparison set 5	*3*	*94*	*80*	*93*	*87*	*92*	*-*	*86*	*43*

The results demonstrate that the performance of A18385B on broad-leaved weeds is comparable for all adjuvants. However for grass weed control the performance of A18385B with Adigor, Fortune, Microbio and the non-ionic surfactants was comparable, but the *Echinochloa crus-galli* control from A18385B with Codacide tended to be lower.

comments of zRMS: dRR point 3.2.1	The mixture contains 3 active substances in which nicosulfuron is required as the grass control component. Prosulfuron and dicamba control of broad-leaved weeds. All ingredients have been widely used for weed control for many years that is why the preliminary tests focused on adjuvants studies. The product formulation does not contain built–in adjuvants therefore external adjuvants were tested to optimize foliar absorption of the herbicide. In trials addition of 8 different adjuvants was tested: oil-based (A12127R (Adigor), Codacide, Fortune), non-ionic (Biopower, Hyspray, Superspray, Trend 90), slurry additive oil-based (Amalgerol). The results on annual and perennial grasses and broad leaved weed showed that the addition of oil-based adjuvant (1,0-1,5 L/ha Adigor) increases the level and decreases the variation of efficacy of A18385B. In trials of comparison of different adjuvants on the performance of A18385B against all broad-leaved weeds, all adjuvants performed comparable. Among grasses, A18385B with Codacide (vegetable oil) performed little worse for control of *Echinochloa crus-galli.* The most suitable adjuvants are oil-based adjuvants such as Adigor or Fortune.

3.2.2 Minimum effective dose tests (KCP 6.2)

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 presented (list of trials shown in Table 3.2-9).

The dose rate ranged from 0.2 kg/ha to 0.4 kg/ha for the Maritime zone and from 0.3 to 0.5 kg/ha for the other EPPO climatic zones. The range reflects 100%, 80% and 60% of the full recommended rates of A18385B, in accordance with the EPPO guideline PP 1/225(1) 'Minimum effective dose'. The efficacy was tested under a range of environmental conditions to fully challenge the product. In the Biological Assessment Dossier (Reference IIIA 6/001) data are presented from trials conducted in EPPO zones North-East and Maritime to fully reflect the range of climatic and agronomic conditions. A summary of results relevant for countries of the Central European Regulatory zone is presented below.

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. The results of the last assessments are presented in the results Tables and Figures. For further detail on materials and methods of the trials, please refer to Section 3.1.

A18385B was always applied in combination with an adjuvant, the results of the combinations with 1.5 L/ha of Adigor or equivalent oil based surfactants are presented.

All trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. All trials were of a randomized complete block design with three to four replicates and a minimum plot size of 12 m^2.

The country for which a registration of this use is intended to be applied is Poland. Results are presented from 28 trials. The results from Germany and Czech Republic were included to support the data from the North-East EPPO zone.

Table 3.2-9: Distribution of trials over years and countries and their affiliation in the EPPO climatic zones.

EU zone	EPPO zone	Country	Year				Sum
			2012	2013	2014	2015	
Central	Maritime	CZ	5	4	1	-	***10***
		DE	4	7	-	-	***11***
	North-East	PL		5	2	5	***12***
Total			***9***	***16***	**3**	**5**	**33**

North-East and Maritime EPPO zones; A18385B applied at 0.5 kg/ha

The dose response effects are demonstrated by the activity of A18385B against a selection of important grass weed species (Table 3.2-10) and by the activity of A18385B against a selection of important broad-leaved weed species (Table 3.2-11).

Table 3.2-10: Minimum Effective Dose of A18385B against important grass weed species in EPPO zones North-East and Maritime

EPPO code	Scientific name	EPPO zone	A18385B (CHA 7980) 0.4 kg/ha				A18385B (CHA 7980) 0.5 kg/ha			
			# trials	Mean	Range	S.D.	# trials	Mean	Range	S.D.
ECHCG	*Echinochloa crus-galli*	Maritime	11	88.9	68-100	10.9	11	89.9	77-100	7.9
		North-East	9	83.1	47-100	16.4	9	83.7	50-100	17.8
		Mean	20	**86.1**	47-100	13.9	20	**87.1**	50-100	13.7

(Results: Appendix 3, table 1, page 119)

Table 3.2-11: Minimum Effective Dose of A18385B against important broad-leaved weed species in EPPO zone North-East

Target weed species	EPPO zone	A18385B + adjuvant											
		0.3 kg/ha				0.4 kg/ha				0.5 kg/ha			
		Mean	Med.	Range	#trial	Mean	Med.	Range	#trial	Mean	Med.	Range	#trial
AMARE	North-East	**93**	93	90-97	2	**93**	93	92-93	2	**96**	96	92-100	2
CHEAL	North-East	**88**	87	73-99	5	**89**	91	75-98	5	**91**	96	75-100	5
LAMPU	North-East	**84**	84	72-97	2	**88**	89	75-99	3	**97**	99	91-99	3
POLCO	North-East	**78**	83	47-100	4	**84**	90	47-100	7	**83**	88	50-100	7
SOLNI	North-East	**53**	53	33-72	2	**73**	75	50-93	3	**80**	80	64-95	3

(Results: Appendix 3, table 2, page 122)

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 sigificant 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 zones.

comments of zRMS: dRR point 3.2.2	**Minimum effective dose tests** The claimed dose rate is 0,4 L/ha and 0,5 L/ha. The dose justification of 0,4 L/ha and 0,5 L/ha of A18385B is supported by data from 28 field efficacy trials. Trials were carried out in the Maritime and NE EPPO zones in maize for the control of grasses and broad-leaved weeds, in 2012 and 2013. In the trials dose rates of A18385B applied post-emergent with adjuvant were tested:0,2 L/ha, 0,3 L/ha, 0,4 L/ha and 0,5 L/ha. In the efficacy trials of A18385B applied post-emergent with adjuvant showed in general a little higher and consistent level of weed control, when it is applied in dose rate 0,5 L/ha. The dose rate of 0,4 L/ha L/ha gave a good level of control for some annual broad-leaved weed. Doses 0,4 L/ha and 0,5 L/ha have demonstrated a good weed control and were considered as the minimum effective doses.

3.2.3 Efficacy tests (KCP 6.2)

Trials in this dossier were carried out by Cheminova (Staehler) and Syngenta, contractor companies and official research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). Relevant GEP certificates from the above mentioned official country testing organizations are located under Point IIIA 6.7.

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region. A summary of results relevant for countries of the Central European Registration zone is presented below.

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”.

As a general rule, the trial layout was according to the randomized complete block design with three to four replicates per treatment. All normal crop husbandry measures were applied to the trials area by the grower, according to crop requirements and in accordance with good agricultural practice. Trials included a range of soil types and locations to determine crop tolerance and efficacy on a number of commercially grown varieties, under a range of conditions. All the trials were placed within regions where maize is commonly grown. Crop and weed growth stages were recorded at the time of application and at the time of assessment(s) using the appropriate BBCH codes. The countries for which a registration is intended is: Poland, with the target dose rate of 0.5 kg/ha

Table 3.2-12: Distribution of trials over years and countries and their affiliation in the EPPO climatic zones.

EU zone	EPPO zone	Country	Year				Sum
			2012	2013	2014	2015	
Central	Maritime	CZ	5	4	1	-	***10***
		DE	4	7	-	-	***11***
	North-East	PL		5	2	5	***12***
Total			***9***	***16***	**3**	**5**	**33**

Results are presented from 33 trials. All of them carried out in the Maritime and North-East EPPO zones being relevant for the Central European Registration zone.

Trials presented in this dossier for the European Central Regulatory zone have been carried out in the following countries: North-East EPPO zone: Poland; Maritime EPPO zone: Czech Republic and Germany. **Table 3.2-12** above, presents the distribution of trials over years and countries and their location in the EPPO climatic zones.

Trials methodology in relation to EPPO

In this section the methodology adopted in the efficacy trials reported in this dossier is summarized. The same methodology was used irrespective of location. Therefore, this methodology section is not further divided by EPPO zones.
A detailed description of trial sites and application details carried out by each official recognized testing facility can be found in tabular form in Appendix 2 of the Biological Assessment Dossier. A list of these official country testing organizations is available in Section 3.7. The relevant GEP certificates are available as hyperlinks to CERTIBASE.

All efficacy trials reported in this Biological Assessment Dossier in maize were documented according to GEP procedures. An overview of the number of trials carried out in the Maritime and North-east and EPPO zones is provided and their approximate location shown in Figure 3.2-3 below. In each trial the 0.5 kgPR/ha was tested. The details on trial methodology in the efficacy trials are shown in Table 3.2-13.

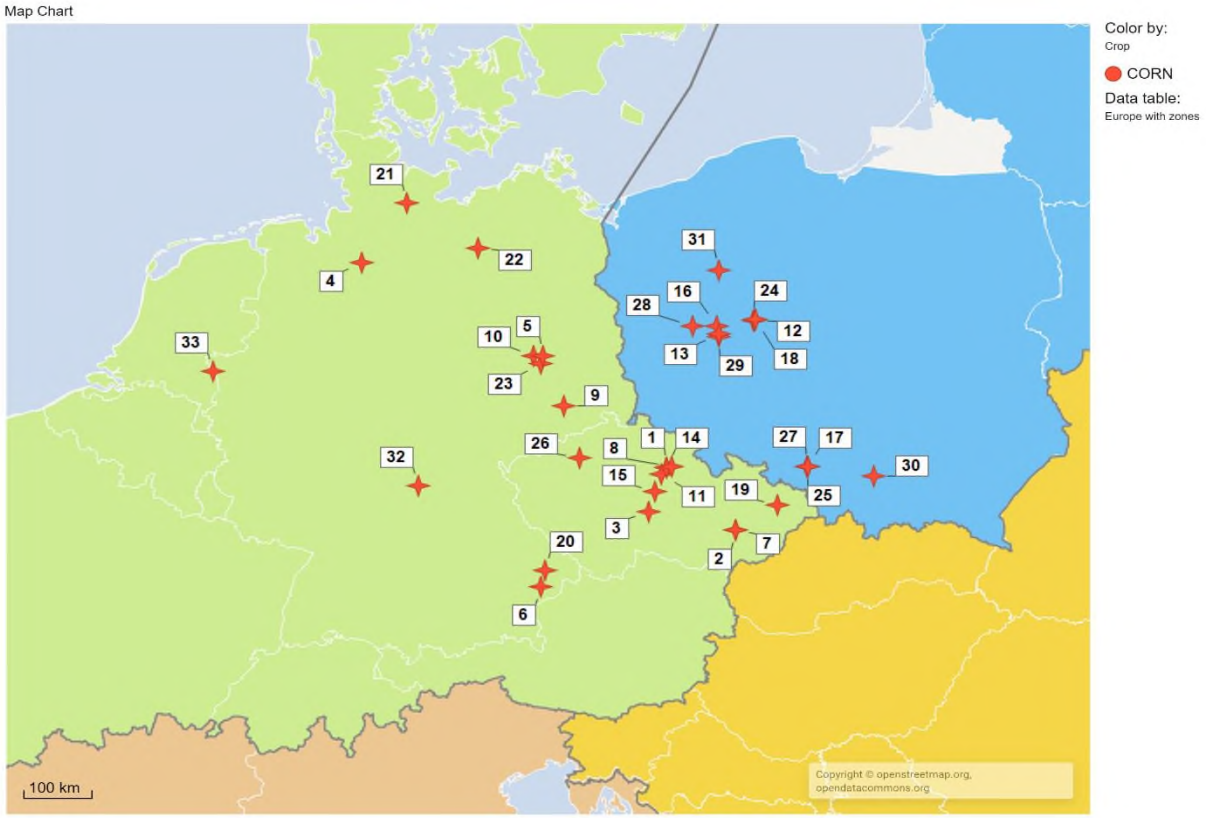


Figure 3.2-3: Distribution of tests carried out with A18385B providing information on the efficacy of A18385B within Europe

Index	Trial number	Index	Trial number	Index	Trial number
1	CZNEZH1022012	16	PLFPZH1122013	31	PLNWZH1012015
2	CZVPZH1052012	17	PLSOZH1272013	32	7980-DE-13-EFF-POST_MA_TR4
3	CZCPZH1032012	18	PLUPZH1392013	33	7980-DE-13-EFF-Post_MA_tr2
4	DEWEZH2352012	19	CZKJZH1052013		
5	DEOSZH3662012	20	DESEZH4432013		
6	DESEZH4412012	21	DENOZH1602013		
7	CZVPZH1042012	22	DEMVZH9112013		
8	CZNEZH1012012	23	DEOSZH3442013		
9	DEESZH3212012	24	PLUP0H1122014		
10	DEOSZH3662013	25	PLSO0H1122014		
11	CZCPZH1032013	26	CZCP0H1012014		
12	PLUPZH1402013	27	PLSOZH1052015		
13	PLFPZH1132013	28	PLUPZH1052015		
14	CZNEZH1052013	29	PLFPZH1042015		
15	CZVPZH1042013	30	PLWEZH0032015		

Table 3.2-13: Details on trial methodology

Guidelines	General guidelines	EPPO PP1/181, PP1/152, PP1/135, 1/241(1)
	Specific guidelines	PP1/050
Experimental design	Plot design	RCBD (33),
	Plot size	12 to 30 m2
	Number of replications	3(27), 4(4)
Crop	Trials per crop	maize
	Varieties per crop	Ciclixx (x3), DKC 39,84, LG 30-220, 3216, DKC 3016, LG 35, LG 32.58 (x2), Ricadinio (x2), DS0553, Agromana, Fisixx, San, Amelior, OP-58 Pioneer, PR39D23, Clarica, Susann, Silvino, Luigi, Total, Dumka, Kadryl, SY Kardona, Millesim, PR39H32, Nimba (x2),
	Sowing period	North-East: 27.04. - 12.05. Maritime: 13.04 - 27.05
Application	Crop stage (BBCH)* at application	North-East: 13-18 Maritime: 12-16
	Timing Pest stage at application (1)	Post-emergence in spring see summary tables for individual weed growth stages
	Number of applications Intervals between applications	1 (33 trials)
	Spray volumes	150-300 L/ha
Assessment	Assessment types	% of weed coverage, number of weeds/m²,
	Assessment dates	7 DAT, 14 DAT, 21 DAT, 45 DAT
Other relevant information	e.g. Soil type, pH (in case of soil active substance …)	Clay Loam, Clay Loam, Humic Sand, Loam, Loamy Sand, Sand, Sandy Loam, Silt Loam, Silty Clay
	e.g. Natural / artificial innoculation…	Natural weed infestation
	e.g. Field / Greenhouse...	Field

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2-14: Overview on test and reference products used for the evaluation

EPPO zone	T / S*	Trade name	Composition	Rates [L(kg)/ha]	N° of trials	Country (where used as standard)
Maritime	T*	A18385B (CHA 7980) & ADIGOR	nicosulfuron (100 g/kg)+prosulfuron (40 g/kg)+dicamba (400 g/kg) & emulsified fatty acid esters ( )	0.5 & 1.5	18/18	CZ, DE
	S	Milagro/ Samson 4 SC	nicosulfuron (40 g/L)	1/1.5	18/18	CZ, DE
		Peak & Trend 90	prosulfuron (750 g/kg) & Isodecyl alcohol ethoxylate (900 g/L)	0.02 & 0.1 %V/V	8/18	DE
		Casper & Trend 90	prosulfuron (50 g/kg)+dicamba (500 g/kg) & Isodecyl alcohol ethoxylate (900 g/L)	0.3 & 0.1 %V/V	18/18	CZ, DE
North-East	T	A18385B (CHA 7980) & ADIGOR	nicosulfuron (100 g/kg)+prosulfuron (40 g/kg)+dicamba (400 g/kg) & emulsified fatty acid esters ( )	0.5 & 1.5	12/12	PL
	S	Milagro	nicosulfuron (40 g/L)	1/1.5	5/12	PL
		Casper & Trend 90	prosulfuron (50 g/kg)+dicamba (500 g/kg) & Isodecyl alcohol ethoxylate (900 g/L)	0.3 & 0.1 %V/V	5/12	PL
		Columbus 51 WG & Trend 90	Mesotrione (118) + Nicosulfuron (39.6) + Rimsulfuron (9.8) & Sodecyl Alcohol Ethoxylate	0.33 KG/HA	6/12	PL

*) T = Test product, S = Reference product

Treatments were applied at GS 10 to 18 (BBCH)of the crop. A18385B was always applied together with an oil-based adjuvant (normally 1.5 L/ha Adigor). Reference products in the trials were for grass weed control Milagro or equivalent nicosulfuron products at rates equivalent to 1.0 and 1.5 L/ha, and for broad-leaved weeds 0.02 kg/ha Peak (+ adjuvant) and 0.3-0.4 kg/ha Casper (+ adjuvant).

Maritime and North-East EPPO zones; A18385B applied at 0.5 kg/ha

The results of the efficacy ratings are presented in detail in Appendix 3. Summaries for A18385B applied at 0.5 kg/ha are presented in **Table 3.2-15** (efficacy against grasses) and

Regarding the control of broad-leaved weeds, A18385B is clearly superior to Peak (+ adjuvant) or Banvel 4S applied at their authorised rates. Compared to Casper (0.3 to 0.4 kg/ha + adjuvant), A18385B is comparable or slightly superior, providing a more complete spectrum.

Table 3.2-16 (efficacy against broad-leaved weeds).

The evaluation is based on the results of 33 GEP compliant field tests.

The results demonstrate that the vast majority of the key grasses and broad-leaved weeds in maize are highly sensitive or sensitive to A18385B. As it is shown in the tables, the test product performs similarly under the different climatic situations (EPPO zones). Seemingly lower performance on grasses (ECHCG, SETSS) in the North-East EPPO zone is a result of 2 trials carried out at the same time on close by locations in Poland which revealed a generally lower performance of the test product. Since the results of *Echinochloa crus-galli* control from a further seven trials carried out in Poland (EPPO zone North-East) are fully comparable to those of the other climatic zones, the lower levels of efficacy are not considered to be dependent on climatic regions. They are just variation.

Compared to the standard products, the grass control (annual and perennial) of the 0.5 kg/ha rate of A18385B is comparable to the reference products being applied at rates equivalent to 1 L/ha of Milagro and comparable to the reference products being applied at rates equivalent to 1.5 L/ha of Milagro.

Table 3.2-15: Overall summary of the efficacy of A18385B + adjuvant against grasses; (% control)

EPPO code	Scientific name	EPPO zone	A18385B (CHA 7980) 0.5 kg/ha				RefP 1[1)]				RefP 2[2)]			
			# trials	Mean	Range	S.D.	#	Mean	Range	S.D.	#	Mean	Range	S.D.
AGRRE	*Elymus repens*	Maritime	5	84.6	57-100	14.5	3	93.3	90-100	4.7	5	88	72-100	9.2
ALOMY	*Alopecurus myosuroides*	Maritime	4	88.5	77-100	10	4	91.5	85-99	6	4	84.5	65-99	15
ECHCG	*Echinochloa crus-galli*	Maritime	11	89.9	77-100	7.9	11	80.8	10-100	32	6	85.3	0-100	27.5
		North-East	9	83.7	50-100	17.8	9	95.2	83-100	5.2	4	97.0	95-100	2.1
		Mean	20	87.1	50-100	13.7	20	89.5	10-100	21.8	10	88.4	0-100	24.1
SETVI	*Setaria viridis*	Maritime	2	95	94-96	1.0	-	-	-		2	99	99	0

[1)] RefP 1: Milagro or equivalent nicosulfuron products at rates equivalent to 1 L/ha of Milagro
[2)] RefP 2: Milagro or equivalent nicosulfuron products at rates equivalent to 1.5 L/ha of Milagro

Key shades: <70 % control | 70-84 % control | 85 - 95 % control | >95 % control

Regarding the control of broad-leaved weeds, A18385B is clearly superior to Peak (+ adjuvant) or Banvel 4S applied at their authorised rates. Compared to Casper (0.3 to 0.4 kg/ha + adjuvant), A18385B is comparable or slightly superior, providing a more complete spectrum.

Table 3.2-16: Overall summary of the efficacy of A18385B + adjuvant against broad-leaved weeds; (in % control)

EPPO code	Scientific name	EPPO zone	A18385B (CHA 7980) 0.5 kg/ha				RefP 1				RefP 2			
			#	Mean	Range	S.D.	#	Mean	Range	S.D.	#	Mean	Range	S.D.
AMAPO	*Amaranthus powellii*	Maritime	1	100	100		1	96	96		-			
AMARE	*Amaranthus retroflexus*	Maritime	5	100	95-100	1.9	5	98	93-100	2.7	1	100	-	-
		North-East	3	94.6	91-100	3.8	2	93.8	85-100	6.4	-	-	-	-
		Mean	***8***	***97.5***	***91-100***	***3.5***	***7***	***95.8***	***85-100***	***5.0***	***1***	***100***		
CAGSE	*Calystegia sepium*	Maritime	1	97	97						1	84	84	
CAPBP	*Capsella bursa-pastoris*	Maritime	2	100	100	0	2	100	100	0	-			
		North-East	4	100	97-100	1.3	4	100	90-100	4.3	-			
		Mean	***6***	***99.5***	***97-100***	***1.0***	***6***	***98.3***	***90-100***	***3.3***	***-***			
CHEAL	*Chenopodium album*	Maritime	13	98.2	94-100	2.1	7	98.6	95-100	2.3	6	89.5	52-100	16-9
		North-East	10	93	75-100	8.2	10	87.5	43-100	16.6	-			
		Mean	***23***	***96***	***75-100***	***6-2***	***17***	***92.1***	***75.100***	***13.9***	***6***	***89.5***	***52-100***	***16.***
CHEPO	*Chenopodium polysp.*	Maritime	1	100	-	-	-				1	100	-	-
CONAR	*Convolvulus arvensis*	Maritime	1	85	-	-					1	77	-	-
		North-East	2	55	47-62	11	2	56	45-67	16				
		Mean	***3***	***64.7***	***47-85***	***15.6***	**2**	**56**	**45-67**	**16**	**1**	**77**	**-**	**-**
EROCI	*Erodium cicutarium*	North-East	1	95	95		1	77	77		-			
EROMO	*Erodium moschatum*	Maritime	1	100	100		-				1	100	100	
GALAP	*Galium aparine*	Maritime	2	91.0	82-100	9.0	1	100			1	13		
		North-East	3	94.4	83-100	7.9	3	92.2	76.7-100	11	-			
		Mean	**5**	**93.1**	**82-100**	**8.5**	**4**	**100**	**76.7-100**	**10.1**	**1**	**13**		
GASPA	*Galinsoga parviflora*	Maritime	2	100	100	0	2	100	100	0	-			
		North-East	2	92.5	92-93	1	2	95	92-98	4	-			
		Mean	***4***	***96.3***	***92-100***	***4***	***4***	***98***	***92-100***	***3***	***-***			
GERPU	*Geranium pusillum*	Maritime	2	100	100	0	2	77	77	33	-			
		North-East	1	82	-	-	2	80	-	-	-			
		Mean	***3***	***94***	***82-100***	***5***	***4***	***78***	***33-100***	***43***	***-***			
IUNCG	*Juncus conglomeratus*	North-East	1	97	97		1	0	0		-			
LAMAM	*Lamium amplexicaule*	Maritime	1	88	88						1	30	30	
LAMPU	*Lamium purpureum*	Maritime	3	97	92-100	5	1	7	7		3	61	23-83	33
		North-East	3	97	91-99	3.9	3	87	65-100	15.8	-			
		Mean	***6***	***97***	***91-100***	***3.9***	***4***	***67***	***7-100***	***37.4***	**3**	**61**	**23-83**	**33**
MATCH	*Matricaria chamomilla*	Maritime	4	100	99-100	1	-				4	98	95-100	2
MATIN	*Matricaria inodora*	Maritime	1	100	100	0	1	100	100	0	-			
		North-East	3	100	100	0	3	100	100	0	-			
		Mean	***4***	100	100	0	3	100	100	0	**-**			
MATMA	*Matricaria maritima*	Maritime	2	100	100	0	2	100	100	0	-			
MENAA	*Mentha arvensis*	Maritime	1	78	78		-				1	53	53	
MERAN	*Mercurialis annua*	Maritime	2	100	100	0	2	99	98-99	1	2	91	83-99	11
POLAM	*Polygonum amphibium*	Maritime	1	99	99		-				1	99	99	
POLAV	*Polygonum aviculare*	North-East	4	84	55-100	18.5	4	49	0-86	30.9	-			
POLCO	*Fallopia convolvulus*	Maritime	11	96	85-100	4.3	6	97	90-100	3.5	7	97	90-100	4.1
		North-East	7	83	50-100	18.7	7	74	53-100	19.1	-			
		Mean	***18***	***91***	***50-100***	***13.7***	***13***	***85***	***53-100***	***18.4***	**7**	**97**	**90-100**	**4.1**
POLLA	*Polygonum lapathif.*	Maritime	**5**	**97**	**85-100**	**5.9**	**3**	**88**	**75-100**	**10.3**	**4**	**91**	**79-100**	**8.2**
POLPE	*Polygonum persicaria*	Maritime	1	100	100	-	1	100	100	-	-			
RAPRA	*Raphanus raphanistrum*	Maritime	1	93	93		-				1	92	92	

EPPO code	Scientific name	EPPO zone	A18385B (CHA 7980) 0.5 kg/ha				RefP 1				RefP 2			
			#	Mean	Range	S.D.	#	Mean	Range	S.D.	#	Mean	Range	S.D.
RORSY	*Rorippa sylvestris*	Maritime	1	99	99		-				1	100	100	
SLYMA	*Silybum marianum*	Maritime	1	80	80		1	73	73					
SOLNI	*Solanum nigrum*	Maritime	5	74	40-100	18.2	2	77	63-91	11.6	3	42	0-99	40.5
		North-East	3	80	64-95	12.9	3	35	0-65	26.8	-			
		Mean	***8***	***76***	***40-100***	***17.8***	***5***	***52***	***0-91***	***30.5***	**3**	**42**	**0-99**	**40.5**
SONAR	*Sonchus arvensis*	Maritime	1	90	90		1	93	93		-			
		North-East	1	100	100		1	90	90		-			
		Mean	***2***	***95***	***90-100***	***5.0***	***2***	***91.5***	***90-93***	***1.5***	**-**			
STEME	*Stellaria media*	Maritime	3	100	100	0	2	97	94-100	4	3	98	93-100	4
THLAR	*Thlaspi arvense*	Maritime	7	100	100	0	6	94	100	0	1	100	100	
		North-East	2	93	93	7	2	93	93	9				
		Mean	***9***	***98***	***88-100***	***4***	***8***	***98***	***87-100***	***4***	***1***	***100***	***100***	
URTUR	*Urtica urens*	Maritime	1	100	100		-				1	96	96	
VERPE	*Veronica persica*	Maritime	3	97	93-100	45.6	2	90	80-100	43.2	1	96	-	
		North-East	1	78	78		1	0	0		-			
		Mean	***4***	***90***	***78-100***	***9.2***	***4***	***60***	***0-100***	***43.2***	**1**	**96**		
VICSS	*Vicia*	Maritime	1	99	99		-				1	99	99	
VIOSS	*Viola species*	Maritime	3	94	83-100	6	1	87	-	-	2	95	92-100	
		North-East	5	92	83-100	9	5	79	62-100	18	-			
		Mean	***8***	***93***	***80-100***	***7***	***6***	***79***	***60-100***	***14.7***	**2**	**95**	**92-100**	

[1] RefP 1: Casper (0.3 - 0.4 kg/ha) + adjuvant
[2] RefP 2: Peak (0.02 kg/ha) + adjuvant **or** Banvel 4S (0.6 - 0.75 L/ha)

Key shades: <70 % control | 70-85 % control | 85 - 95 % control | >95 % control

In **Table 3.2-17** the weed species are classified according to their sensitivity to A18385B applied at 0.5 kg/ha. The classification is made according to Appendix I of Regulation SANCO/10055/2013 Rev. 4 (October 3rd 2013), based on the mean across the trial results. Only weeds represented by at least 3 results are regarded, however this does not replace individual MS systems for expressing control on national labels.

Table 3.2-17: Weed control spectrum of A18385B (0.5 kg/ha) + adjuvant in maize

Scientific name	English common name	EPPO code
Highly sensitive (95 – 100 %)		
Amaranthus species	amaranthus	AMASS
Capsella bursa-pastoris	shepherd's-purse	CAPBP
Chenopodium album	fat hen	CHEAL
Galinsoga parviflora	smallflower galinsoga	GASPA
Lamium purpureum	red deadnettle	LAMPU
Matricaria species	chamomile	MATSS
Fallopia convolvulus	wild buckwheat	POLCO
Polygonum lapathifolium	pale smartweed	POLLA
Stellaria media	common chickweed	STEME
Thlaspi arvense	field pennycress	THLAR
Sensitive (85 - 94.9 %)		
Alopecurus myosuroides	blackgrass	ALOMY
Echinochloa crus-galli	cockspur	ECHCG
Elymus repens	quackgrass	AGRRE
Veronica persica	persian speedwell	VERPE
Viola species	violet	VIOSS
Geranium pusillum	smallflower geranium	GERPU
Galium aparine	-	GALAP
Moderately sensitive (70 – 84.9 %)		
Polygonum aviculare	prostrate knotweed	POLAV
Solanum nigrum	black nightshade	SOLNI

Scientific name	English common name	EPPO code
Moderately tolerant (50 – 69.9 %)		
Convolvulus arvensis	field bindweed	CONAR
Tolerant (<50 %)		
-	-	-

Overall conclusions

Based on the results of 33 field trials [EPPO zone Maritime (21); EPPO zone North-East (12), EPPO zone] carried out between 2012 and 2015 the following can be 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.

Study Comments: 3.2.3 dRR point 3.2.3	

EN: Evaluator conclusion:

Control of weeds in the North-East EPPO climatic zone (Poland)
Post - emergence weeds control

The applicant submitted 35 trials carried out in 2012, 2013, 2014 and 2015 on *Zea mays* (BBCH 12-18) in Poland and in the Czech Republic and Germany – bordering countries.
The Czech Republic and Germany belong to the Maritime EPPO climatic zone. The Applicant has presented document of climate comparability between the region of Wielkopolskie and Hannover, Luneburg, Mecklenburg-Vorpommern, Sachsen-Anhalt, Unterfranken to indicate that data from DE and CZ (the Maritime EPPO climatic zone) are relevant for Poland. In 5 documents have shown high similarity between above mentioned regions.

The minimal number of an individual weed per m^2 in the trials should be 5, to include such trials in the assessment. In the following reports the number of weeds per m^2 were not adequate, so those trials were excluded from the assessment:
DEMVZH9112013: SETVI - 4 %
PLUP0H1122014: SETVI – 4 pl./m^2
PLUPZH1392013: AMARE - 4 pl./m^2, GASPA - 4 pl./m^2, POLAV - 4 pl./m^2, POLAV - 4 pl./m^2, POLCO - 4 pl./m2, SOLNI – 2,5 pl./m^2, SONAR - 4 pl./m^2, THLAR – 4,5 pl./m^2
PLSOZH1272013: CHEAL - 2 pl./m^2, LAMPU – 2,5 pl./m^2, POLCO – 2,5 pl./m^2, SOLNI – 2,5 pl./m^2
PLWEZH0032015: GALAP – 2 pl./m^2
PLUPZH1402013: GASPA - 4 pl./m^2, GERPU - 4 pl./m^2, POLAV - 4 pl./m^2, POLCO - 4 pl./m^2, THLAR - 4 pl./m^2
PLSOZH1052015: MATIN - 4 pl./m^2, POLAV – 4 pl./ m^2, SOLNI - 4 pl./m^2
7980-DE-13-EFF-Post_MA_tr2: POLCO – 2,2%
S12-00993-03: POLCO – 4,3%
DEOSZH3662012: STEME – 2%, VIOAR – 3 pl./m^2
DESEZH4432013: THLAR - 4 pl./m^2

Additionally, the evaluator considered the efficacy results of at least 2 trials for each of the weed species assigned. The data from one trial for one weed species are not sufficient to prove the effectiveness of the product. What is more where species of weeds were not determined, results of these trials might be only supportive for the sufficient number (at least 2) of trials conducted for weeds of the same genus and different species (in the below table figures in grey). As a result data presented for following weeds are not sufficient: SETSS, AMAPO, CAGSE, CHEPO, EROCI, EROMO, IUNCG, LAMAM, MENAA, MERAN POLAM, POLAV (only1 trial with sufficient weed density of 5 pl./m^2), POLPE, RAPRA, RORSS, SLYMA, SONAR, URTUR, VICSS.
Data from FR, UK, CH, AT were not taken under consideration to evaluate efficacy for ALOMY, MATCH, AGREE, SOLNI, MERAN, POLLA because those MS belongs to Maritime/Mediterranean EPPO climatic zones.

Efficacy trials were carried out by organizations that are officially recognized as competent to carry out efficacy testing in accordance with Regulation (EC) 284/2013 by the authorities in the relevant countries. All trials have been conducted according to GEP. List of test facilities is contained in the Table 3.2-18.

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:
1. PP 1/181 (3/4) Conduct and reporting of efficacy evaluation trials including good experimental practice.
2. PP 1/135 (3/4) Phytotoxicity assessment
3. PP 1/50 (3) Weeds in maize
4. PP 1/152(3/4) Design and analysis of efficacy evaluation trials

Results of experiments (data on effectiveness) are contained in Appendix 3 to the BAD. Trials were of randomized block design with a minimum of three or four replicates. Details on trial sites, applications are contained in Appendix 2 to the BAD. The susceptivity of weeds were evaluated according to the criteria presented below, established for PL.

Weed species are classified as:

susceptible (S) –	85%
moderately susceptible (MS) -	70-84,9%
moderately tolerant (MT)	60 -69,9%

tolerant (T) < 60%

The tested herbicide was applied at the rates: 0,2 kg/ha, 0,3 kg/ha, 0,4 kg/ha and 0,5 kg/ha of A18385B together with oil-based adjuvant at the rates 1,0 L/ha and 1,5 L/ha in *Zea mays* as a single application against weeds on different varieties of maize: Ciclixx, DKC 39,84, LG 30-220, 3216, DKC 3016, LG 35, LG 32.58, Agromana, Fisixx, San, Amelior, OP-58 Pioneer, PR39D23, Clarica, Susann, Silvino, Luigi, Total, Dumka, Kadryl, SY Kardona, Millesim, PR39H32, Nimba, P8000, LEG 3216, Torres. Spray volume applied on the crop was 150 – 400 l/ha.

In accordance with GAP table results are presented below for two rates: 0,4 kg/ha and 0,5 kg/ha (plus oil-based adjuvant 1,0 L/ha or 1,5 L/ha). Assessment was done about 50 – 60 DA-A.

Efficacy against grass weeds species in maize:

Weed species (no. of trials)	Efficacy A18385B [%]			
	0,4 kg/ha	0,5 kg/ha	Ref. 1	Ref. 2
AGRRE (4)	83,3 (63-100)	83,5 (57-100)	95,0 (90-100)	88,0 (72-100)
ECHCG (20)	86,3 (47-100)	87,1 (50-100)	89,5 (10-100)	88,4 (0,0-100)

Efficacy against broad-leaved weeds species in maize:

Weed species (no. of trials)	Efficacy A18385B [%]			
	0,4 kg/ha	0,5 kg/ha	Ref.1	Ref. 2
AMARE (7)	96,8 (91,7 – 100)	96,8 (91,7 – 100)	95,05 (85 – 100)	100
CAPBP (6)	99,7 (98,0-100)	99,5 (97-100)	98,3 (90-100)	100
CHEAL (22)	94,7 (75 – 100)	95,8 (75 – 100)	91,9 (43 – 100)	89,5 (52 – 99)
CONAR (3)	63,7 (35-78)	64,7 (47-85)	56,0 (45-67)	77,0
GALAP (4)	91,7 (76,7 – 100)	91,3 (82 – 100)	88,3 (76,7 – 100)	13
GASPA (2) *	100	100	100	-
GERPU (2)**	94 (87-100)	100	77 (53-100)	
LAMPU (5)	92,4 (80 – 100)	98,1 (92 – 100)	68 (7 - 100)	61 (23 – 83)
MATCH (2)	98,5 (98-99)	99	96	97 (95-99)
MATIN (3)	100	100	100	-
MATMA (2)	100	100	100	-
MERAN (2)	100 (99-100)	100	99 (98-100)	91 (83-99)
POLCO (13)	93,6 (83,3 – 100)	94,9 (85 – 100)	87,8 (53,3 – 100)	97 (96- 100)
POLLA (3)	99 (99-100)	99 (99-100)	100	89,5 (79-100)
SOLNI (4)	64 (23 - 83)	71,25 (40-100)	63	35,3 (0,0-99)
STEME (2)	97 (94 – 100)	100	97 (94 – 100)	96,5 (93 – 100)
THLAR (6)***	99,3 (98 – 100)	100	100	-
VERPE (3)	86 (75-100)	90 (78-100)	60 (0-100)	-
VIOAR (6)****	92,2 (87 – 100)	91 (83 – 100)	80,3 (60 – 100)	

* excluded 2 polish trials showed high efficacy 90,5 % and 92,5%
** excluded polish trial showed high efficacy 92 % and 82%
*** excluded 2 polish trials showed high efficacy 94 % and 93%
**** The trial DENOZH1602013, where *Viola tricolor* was tested, is only supportive for VIOAR testing.

50 – 60 days after application the following target weed species were categorized as:

- susceptible (S):
for dose rate 0,4 kg/ha: ECHCG, AMARE, CAPBP, CHEAL, GALAP, GASPA, GERPU, LAMPU, MATCH, MATIN, MATMA, POLCO, POLLA, STEME, THLAR, VERPE, VIOAR
for dose rate 0,5 kg/ha: ECHCG, AMARE, CAPBP, CHEAL, GALAP, GASPA, GERPU, LAMPU, MATCH, MATIN, MATMA, POLCO, POLLA, STEME, THLAR, VERPE, VIOAR

- moderately susceptible (MS)
for dose rate 0,4 kg/ha: AGRRE
for dose rate 0,5 kg/ha: AGRRE, SOLNI

- moderately tolerant (MT)
for dose rate 0,4 kg/ha: CONAR, SOLNI
for dose rate 0,5 kg/ha: CONAR

CONAR showed week (moderately tolerant) susceptibility on A18385B at dose rate 0,4 kg/ha and 0,5 kg/ha. There is a need to make an appropriate label statement.

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.

The application of A18385B at 0,4 kg/ha and 0,5 kg/ha (plus oil-based adjuvant 1,0 L/ha or 1,5 L/ha, spray volume 150 - 400 l/ha) provides benefit against weeds in maize comparable or better with standard products: Milagro or equivalent nicosulfuron products.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The risk for the development of resistance of target weed species was analysed following EPPO guideline PP1/213(4).

The history based analysis of the inherent risk of target weed species to develop resistance to herbicides demonstrates that based on the International Survey of Herbicide Resistant Weeds, in maize crop 9 grass weed species and 26 broadleaved weed species resistant to herbicides across Europe. Except for *Sorghum halepense*, all are resistant to Group C1 (photosystem II inhibitors) and especially to the triazine class since the 1980s. One case of multiple resistance to Group C2 (ureas and amides) has been reported in an *Amaranthus retroflexus* population in Germany. In recent years, more cases of resistance to Group B (ALS inhibitors) have been reported on grass weeds typically occurring in maize, such as *Digitaria sanguinalis*, *Echinochloa crus-galli*, *Setaria viridis* and *Sorghum halepense* (including explicitly to nicosulfuron). There is no evidence of weed resistance in maize to Group O to which dicamba belongs.
Consequently, in Europe the risk of resistance to A18385B inherent in maize weed species may be considered medium to high for grass weeds and low for broadleaved weeds.
There is no evidence of weed resistance in maize crop to group O (to which dicamba belongs) and only three cases of resistance to group B has been reported: *Echinochloa crus-galli* biotypes resistant to 4 of the five group B classes (and explicitly to nicosulfuron) have been detected in Italy in 2007.Setaria viridis biotypes resistant to 4 of the five group B classes have been detected as well in Italy in 2007. And in *Sorghum halepense.*

Consequently, 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. .

Due to the diversity of agricultural practices and herbicide regimes available in the EU to reduce the selection pressure of A18385B, the agronomic risk of evolving weeds resistance following A18385B use can be considered low.

The evaluation led to the conclusion that the resistance risk in the use of A18385B in Europe is considered as acceptable. The analysis of the risk inherent in the active ingredients dicamba, nicosulfuron and prosulfuron, the risk inherent in maize weed species and the agronomic risk concludes that the risk of the target weed species to develop resistance to A18385B can be considered acceptable if A18385B is applied according to the proposed use pattern. For details please refer to the Biological Assessment Dossier.

Comments of zRMS:	A18385B contains three active ingredients: dicamba classified by HRAC to the group O (synthetic auxins), nicosulfuron and prosulfuron classified by HRAC to the group B (inhibition of the acetolactate synthase enzyme (ALS)). In Europe 5 resistant biotypes of weeds to group O herbicides were found mainly in cereals. In relation to ALS herbicides 24 resistant biotypes od weeds were documented in Europe. Multiple resistances of weed to synthetic auxins (HRAC Group O) are known mainly with ALS inhibitors (Group B), for ALS inhibitors, are documented with herbicides in various HRAC groups, but mainly in Group A (ACCase inhibitors). The Applicant analyzed the risk of resistance to A18385B in a two-stage process: resistance risk assessment and resistance risk management, according to the EPPO guidelines PP 1/213 (2). The risk of resistance to active substances contained in A18385B might be considered acceptable, if A18385B is used according to the label instructions. The applicant proposed place on the label rules for the resistance management strategy of A18385B: *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)* Nevertheless in case any new information which would change the resistance risk analysis regulatory authorities should be informed about it.

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

Special selectivity trials in this Biological Assessment Dossier were carried out by Syngenta organizations and contractor companies, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). A list of these official country testing organizations is shown in **section 3.7**. The relevant GEP certificates are available as hyperlinks to CERTIBASE.

On the basis of the EPPO standard 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

Materials and Methods

In this section the methodology adopted in the special weed free selectivity trials reported in this dossier is summarized. The same methodology was used irrespective of location. Therefore, this methodology section is not further divided by EPPO zones.

A detailed description of trial sites and application details carried out by each official recognized testing facility can be found in tabular form in **Appendix 2** of the BAD document. A list of these official country testing organizations is available in **Section 3.7**.

Information on trials submitted in this chapter (3.4: Adverse effects on treated crops) are summarised in Table 3.4-1 below. Figure 3.4-1 visualizes the trial distribution for the Maritime and North-East EPPO zone on a map.

Table 3.4-1: Overview of tests carried out with A18385B providing information on the crop safety under weed free conditions

EU zone	EPPO zone	Country	Year			Sum
			2012	2013	2015	
Central	Maritime	CZ	2	3	-	***5***
		DE	3	5	-	***8***
	North-East	PL		5	***3***	***8***
Total			***5***	***13***	**3**	**21**

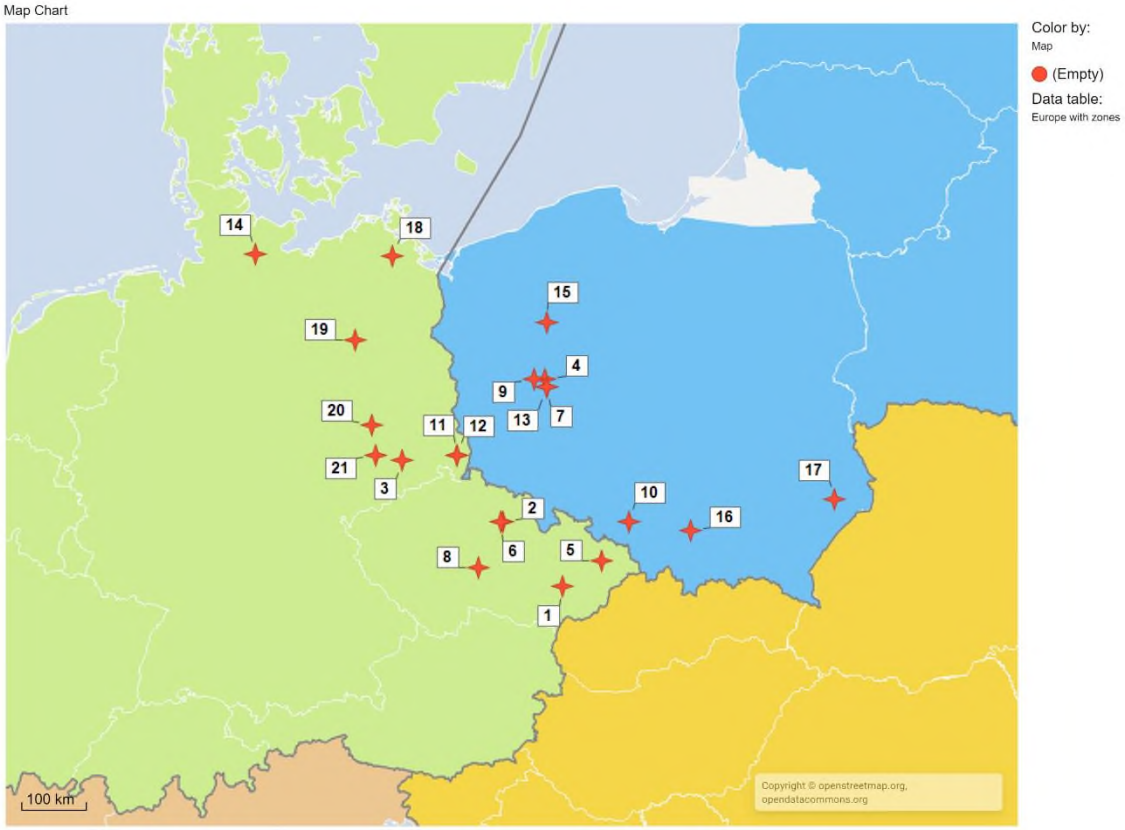


Figure 3.4-1: Distribution of tests carried out with A18385B providing information on the crop safety under weed free conditions within Europe

Trial number	Index	Trial number	Index
CZVPZH1042012	1	DEESZH3892013	12
CZNEZH1012012	2	**PLFPZH1132013**	13
DEESZH3212012	3	DENOZH1602013	14
PLFPZH1142013	4	**PLBCZH1512015**	15
CZKJZH1062013	5	**PLWEZH1012015**	16
CZNEZH1062013	6	**PLULZH1012015**	17
PLFPZH1152013	7	7980-12-DE...SEL-POST-MA tr1	18
CZCPZH1042013	8	7980-12-DE...SEL-POST-MA tr2	19
PLUPZH1412013	9	7980-DE-13-SEL-MA_tr2	20
PLSOZH1282013	10	7980-DE-13-SEL-MA_tr1	21
DEESZH3902013	11		

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Introduction

Specific crop tolerance trials were set up to analyse the crop safety of A18385B under weed-free conditions. In order to gain a good understanding of any crop safety issues, trials were performed in maize growing countries of the Maritime and North-East EPPO zone. To evaluate the crop safety regular phytotoxicity assessments were performed following an application of A18385B at the rate of 0.5 kg/ha and 1.0 kg/ha post emergence. The 1.0 kg/ha rate is designed to test the crop safety of A18385B following an accidental spray overlap which could occur in a commercial farming situation. In order to further evaluate the crop safety of A18385B at the single and double timing, the vast majority of crop tolerance trials featured a yield and yield quality analysis. Trials were conducted across multiple seasons to provide a detailed study of A18385B.

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

Trials methodology in relation to EPPO
Trials were conducted according to the EPPO guidelines stated in Table 3.4-3, which also summarises the methodology section described hereafter in tabular form.

Full details of the sites and applications are provided in Appendix 2. The hyperlinks to the GEP certificates of the official testing organisation are provided in Annex Point IIIA 3.7.

As a general rule, the trial layout was according to the randomized complete block design with four replicates per treatment. Plot sizes ranged from 20 - 45 m^2. All normal crop husbandry measures were applied to the trials area by the grower, according to crop requirements and in accordance with good agricultural practice. Trials included a range of soil types and locations to determine crop tolerance on a number of commercially grown maize varieties, under a range of conditions. All the trials were placed within regions where maize are commonly grown. Crop growth stages were recorded at the time of application and throughout the trial using the appropriate BBCH codes.

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).

Crop phytotoxicity was assessed at specific timings after application. Assessment timings were defined based on the physiological sensitivity of the maize crop to herbicides:

7, 14 and 28 days after application

at tasseling of the corn : BBCH 51-59

All assessments were on an overall plot basis in comparisons with the untreated plot on a linear scale (from 0% = no symptoms to 100% = maximum damage), and individual symptoms were recorded where appropriate. Where no phytotoxicity was observed, this was generally recorded within the individual trial reports. In addition to phytotoxicity, yield and quality parameters were assessed in the crop tolerance trials. Total plot sizes varied from 20 - 45 m^2 were harvested. A range of yield and quality parameters were analysed. Please refer to Section 3.4.2 and Section 3.4.3 for the results of the gross yield and yield quality assessments respectively.

All assessment data was analysed statistically by employing the Student-Newman-Keuls (SNK) method. The SNK method is a test for simultaneous comparisons of multiple means which controls error rates among tests of multiple groups of means (multiple range test). Please note that the results in the summary tables were extracted from trials reports where other treatments of no relevance to this submission may have been included. As statistical analyses were conducted across the whole range of treatments, significance letters relate to the whole treatments list and not just to the data shown in the extracted tables.

Individual trial data are located in the respective reports cited in the reference list in Appendix 1.

Table 3.4-2: Details on crop selectivity trial methodology

Guidelines	General guidelines	PP1/135 (3)(4), PP1/152 (3)(4), PP1/181 (3)(4)
	Specific guidelines	PP1/050(3)
Experiment Design	GEP	Yes
	Plot design	Randomised Block Design (21)
	Plot size	20 to 45m^2
	Number of replications	4 (19 trials), 3 (2 trials)
Crop	Trials per crop	21
	Varieties	LG 32.58, Ciclixx, Ricadinio, DS0553, PR39F58-Pionier, San, Libreto, P7524, PR39D23, P8000, Geoxx, Silvino, SY Kardona, MAS 22R, Colisee
	Sowing period	for details please refer to Appendix 2
	Trial location	Maize growing areas in the concerned countries, for details please refer to Appendix 2
Application	Crop stage at application	BBCH 10-17
	Application period	May (6), Jun (11)
	Number of applications	1 (21) 2 to simulate accidental spray overlap (21)
	Application technique	Plot sprayers; nozzles: flat fan; spray pressure: 0.3 to 3.5 bar
	Spray volumes	150 to 300 l/ha;
Assessment	Assessment types	Visual estimation of % phytotoxicity compared to the untreated (0 % = no symptoms to 100 % = maximum damage) individual symptoms were recorded where appropriate
	Assessment dates	As a rule, 3 to 4 assessment timings based on the physiological sensitivity of the maize crop
Other information	Soil types	Clay Loam, Humic Sand, Loam, Lomy Sand Loess, Sandy Loam, Silty Clay

Reference Products

The test and reference products used in the trials are listed in Table 3.4-3

Table 3.4-3: Overview on test and reference products used for the evaluation

EPPO zone	T / S*	Trade name	Composition	Rates [L(kg)/ha]	N° of trials	Country (where used as standard)
Maritime	T*	A18385B (CHA7980) & ADIGOR	nicosulfuron (100 g/kg)+prosulfuron (40 g/kg)+dicamba (400 g/kg) & emulsified fatty acid esters ( )	0.4-0.8/0.5-1.0 & 1.5-3.0	13/13	CZ, DE
	S	Banvel 4 S (A7254)	dicamba (480 g/L)	0.6-1.2	11	CZ, DE
		Mais-Banvel WG	dicamba (700 g/kg)	0.5-1	4	DE
		Milagro	nicosulfuron (40 g/L)	1-2	3	DE
North-East	T*	A18385B (CHA7980) & ADIGOR	nicosulfuron (100 g/kg)+prosulfuron (40 g/kg)+dicamba (400 g/kg) & emulsified fatty acid esters ( )	0.4-0.8/0.5-1.0 & 1.5-3.0	8/8	PL
	S	Banvel 4 S (A7254)	dicamba (480 g/L)	0.6-1.2	4/8	PL
	S	Columbus 51 WG & Trend 90	Mesotrione(118)+ Nicosulfuron(39.6)+Rimsulfuron(9.8) & Sodecyl Alcohol Ethoxylate	0.33 kg/ha	3/8	PL
	S	Mocarz 75 WG & OLBRASS 88 EC	Tritosulfuron (50%)+ dicamba (25%) & OLBRASS	0.2 kg/ha & 1 L/ha	5/8	PL

*) T = Test product, S = Reference product

Overall summary of phytotoxicity to host crops

54 trials (33 efficacy trials and 21 selectivity trials) were rated for adverse effects of A18385B applied at the target rates of 0.4 and 0.5 kg/ha (+ adjuvant) on the target crop. The results of 5 variety trials are presented separately. In **Błąd! Nie można odnaleźć źródła odwołania.** (efficacy trials) and **Błąd! Nie można odnaleźć źródła odwołania.** (crop safety trials) the frequency and the magnitude (maximum) of observations of phytotoxic symptoms are presented.

More information on the behaviour of phytotoxicity and its impact on crop yield in the single trials showing adverse effects of > 5% is shown in Table 3.4-6 (efficacy trials) and in Table 3.4-7 (crop safety trials).

Table 3.4-4: Frequency and magnitude of phytotoxicity* observations of target rates in efficacy trials

EPPO zones	Maritime			North-East		Across EPPO zones	
Products:	A18385B		RefP	A18385B	RefP	A18385B	RefP
Phytotoxicity	0.4 kg/ha + adjuvant	0.5 kg/ha + adjuvant	X rate	0.5 kg/ha + Adjuv.	X rate	0.5 kg/ha + Adjuv.	X rate
Maximum	7.7	9.0	6.7	20.0	20.0	20	20
N° of tests: 0%	18	18	19	11	11	28	30
N° of tests: >0-5%	2	2	0	0	0	4	0
N° of tests: >5-15%	1	1	2	0	0	1	2
N° of tests: >15%	0	0	0	1	1	0	1
N° of tests	21	21	21	12		33	

*) phytotoxicity = % general phytotoxicity

Table 3.4-5: Frequency and magnitude of phytotoxicity* observations of target rates in crop safety trials (only N dose rate)

EPPO zones	Maritime		North-East		Across EPPO zones	
Products:	A18385B	RefP	A18385B	RefP	A18385B	RefP
Phytotoxicity	0.5 kg/ha + Adjuv.	X rate	0.5 kg/ha + Adjuv.	X rate	0.5 kg/ha + Adjuv.	X rate
Maximum	5.0	5.0	15.0	10.0	15	10
N° of tests: 0%	11	12	5	5	16	17
N° of tests: >0-5%	1	1	2	2	3	3
N° of tests: >5-15%	1	0	1	1	2	1
N° of tests: >15%	0	0	0	0	0	0
N° of tests	**13**		**8**		**21**	

*) phytotoxicity = % general phytotoxicity

Table 3.4-6: Phytotoxicity of the target rate in efficacy trials showing adverse effects > 5 %

Trial Reference N°	Cultivar	Application		DAA	Untrt	A18385B	RefP
		Date	GS		[%]	[%]	[%]
DEMVZH1132013	Luigi	30.05.13	13-14	11-21	0 c	5.0 bc	6.7 bc
				23-38	0	0.0	0.0
DENOZH1602013	Silvino	12.06.13	13-16	11-21	0 d	7.7 ab	6.0 bc
				23-38	0 c	3.7 b	6.0 b
				54-70	0	0.0	0.0
DESEZH1442013	Susann	21.05.13	14-15	11-21	0	0.0	0.0
				23-38	0	0.0	0.0
				54-70	0 a	**5.0 a**	0.0 a
PLFPZH1132013	San	19.06.13	15	11-21	0 e	20.0 b	20.0 b
				23-38	0 b	13.3 ab	16.7 ab
				39-53	0 b	10.0 ab	6.7 ab

Table 3.4-7: Phytotoxicity and yield of the target rate in crop safety trials showing adverse effects > 5 %

					Phytotoxicity			Yield		
Trial Reference N°	Cultivar	Application		DAA	Untrt	A18385B	RefP	Untrt	A18385B	RefP
		Date	GS		[%]	[%]	[%]	[t/ha]	[% of Untrt]	
7980-DE-13-SEL-MA_tr2	Colisee	23.05.13	13-13	11-21	0	0.0	0.0			
				22-36	0 c	10.0 b	0.0 c			
				54-76	0	0.0	0.0	314.8 a	96 a	105 a
PLFPZH1152013	San	19.06.13	15	5-10	0 d	5.0 ab	1.0 a-d			
				11-21	0 d	15.0 ab	10.0 abc			
				22-36	0 d	15.0 abc	7.5 bcd	69.3 a	95 a	91 a

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.

Crop tolerance of the double rate

Materials and methods

Please refer to section 3.4.1 for the description of materials and methods of the crop safety trials.

Results

21 selectivity trials were rated for adverse effects of A18385B applied at the double rates of 0.8 and 1.0 kg/ha (+ adjuvant) on the target crop. The results of 3 variety trials are presented separately. In Table Table 3.4-8 the frequency and the magnitude (maximum) of observations of phytotoxic symptoms are presented.

More information on the behaviour of phytotoxicity and its impact on crop yield in the single trials showing adverse effects of > 5% is shown in Table 3.4-9

Table 3.4-8: Frequency and magnitude of phytotoxicity* observations of double rates in crop safety trials

EPPO zones	Maritime			North-East		Across EPPO zones	
Products:	A18385B		RefP	A18385B	RefP	A18385B	RefP
Phytotoxicity	0.8 kg/ha + adjuvant	1.0 kg/ha + adjuvant	2X rate	1.0 kg/ha + Adjuv.	2X rate	2X rate + Adjuv.	2X rate
Maximum	35.0	**7.5**	10.0	**13**	18	**7.5**	18
N° of tests: 0%	13	**11**	13	**5**	5	**16**	18
N° of tests: >0-5%	1	**1**	1	**2**	2	**3**	3
N° of tests: >5-15%	1	**1**	2	**1**	0	**2**	2
N° of tests: >15%	1	**0**	0	**0**	1	**0**	1
N° of tests	16	13	16	8		24	

*) phytotoxicity = % general phytotoxicity

Table 3.4-9: Phytotoxicity and yield of the double rate in crop safety trials showing adverse effects > 5 %

					Phytotoxicity			Yield		
Trial Reference N°	Cultivar	Application		DAA	Untrt	A18385B 2X	RefP 2X	Untrt	A18385B 2X	RefP 2X
		Date	GS		[%]	[%]	[%]	[t/ha]	[% of Untrt]	
DESWZH5222012	DS0553	25.05.12	14-15	5-10	0 d	2.5 bc	2 c			
				11-21	0 d	**7.5 ab**	8.5 a			
				22-36	0 d	7.3 a	8.3 a			
				38-53	0 c	4 b	6.5 a	113.2 a	92 a	93 a
7980-DE-13-SEL-MA_tr2	Colisee	23.05.13	13-13	11-21	0	0	0			
				22-36	0 c	**35 a**	8.8 b			
				54-76	0	30	**10**	314.8 a	86 b	99 a
PLFPZH1152013	San	19.06.13	15	5-10	0 d	1 a-d	7.5 bcd			
				11-21	0 d	**13 abc**	15 ab			
				22-36	0 d	13 abc	**18 bc**	69.3 a	98 a	90 a

The results show that A18385B applied at the double rate is still safe on maize. In 19 of 21 crop safety trials no clearly visible (> 5 %) adverse effects caused by the double rate of A18385B were observed. Phytotoxicity symptoms in the range of maximum >5 to 13 % were observed in 2 trials and in 1 trial the maximum assessed effects were higher than 15 % (up to 35 %). As with the target rate, 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.

While in 2 of the 3 cases of observed phytotoxicity in harvested trials, yield was not reduced significantly by A18385B if applied at double rate, in 1 trial (7980-DE-13-SEL-MA_tr2) it is likely, that the height reduction of up to 35 % is correlated to the significantly lower yield of forage maize (-14 % compared to the untreated control in the absence of weeds).

Crop tolerance in different cultivars

In 2012(3) and in 2013(2) five variety tests were carried out with relevant maize hybrids from different breeding companies. For materials and methods, please refer to Section 3.4.1.1. The results are presented in Table 3.4-10 and in Table 3.4-11.

Despite the fact, as known from nicosulfuron containing products and as already shown above, occasionally phytotoxicity cannot be excluded, no variety dependent differences in crop tolerance have been observed.

In trial (7950 + 7980 VAR trial 1) up to 30 % growth inhibition was observed which disappeared largely throughout the season. The trial data gives no further explanation for the reasons of the effects which were visible in all tested plots (test and reference products). Although the highest rate of A18385B (1 kg/ha) showed the highest level of symptoms, no clear dose response has been observed: The rate of 0.8 kg/ha showed less growth inhibition on all maize hybrids than the rate of 0.5 kg/ha. Despite the phytotoxicity symptoms, it can be concluded that there is no indication for genetically based sensitivity differences of the tested hybrids.

Initial irregular occurring low level symptoms in trial (7950 + 7980 VAR trial 2) were transient and disappeared quickly. There is no indication for genetically based sensitivity differences.

The results are in line with the observations made in the efficacy and the selectivity tests discussed above, where A18385B was applied on the respective maize hybrids which were planted on farmer's field. Also in those trials no varietal dependent differences in crop tolerance were observed.

Table 3.4-10: Phytotoxicity results of 3 variety trials carried out in Germany in 2012 with A18385B (Spandis)

	Trial																	
	7950 + 7980 VAR trial 1						7950 + 7980 VAR trial 2						7950 + 7980 VAR trial 3					
Cultivar	A18385B (+ adjuvant)				Milagro		A18385B (+ adjuvant)				Milagro		A18385B (+ adjuvant)				Milagro	
	0.4 kg/ha	0.5 kg/ha	0.8 kg/ha	1.0 kg/ha	1.0 L/ha	2.0 L/ha	0.4 kg/ha	0.5 kg/ha	0.8 kg/ha	1.0 kg/ha	1.0 L/ha	2.0 L/ha	0.4 kg/ha	0.5 kg/ha	0.8 kg/ha	1.0 kg/ha	1.0 L/ha	2.0 L/ha
Atletico	12.5	20	15	**30**	10	20	0	10	10	**0**	0	0	0	0	0	**0**	0	0
DKC3307	12.5	20	15	**30**	10	20	0	15	0	**0**	0	0	0	0	0	**0**	0	0
DKC3409	12.5	20	15	**30**	10	20	0	0	0	**0**	0	0	0	0	0	**0**	0	0
ES Prolog	12.5	20	15	**30**	10	20	0	0	0	**23**	0	10	0	0	0	**0**	0	0
Fernandez	12.5	20	15	**30**	10	20	0	0	0	**0**	0	0	0	0	0	**0**	0	0
LG 3220																		
Logo	12.5	20	15	**30**	10	20	0	0	0	**0**	0	0	0	0	0	**0**	0	0
Masetto	12.5	20	10	**35**	10	17.5	0	0	0	**0**	0	0	0	0	0	**0**	0	0
NK																		
Falkone	12.5	20	15	**30**	10	22.5	0	10	0	**0**	0	0	0	0	0	**0**	0	0
P800	12.5	20	15	**30**	10	20	0	13	0	**0**	0	0	0	0	0	**0**	0	0
Saludo	12.5	20	15	**30**	10	20	0	13	0	**10**	0	13	0	0	0	**0**	0	0
Sherley	12.5	20	15	**30**	10	15	0	10	0	**10**	0	0	0	0	0	**0**	0	0
Susann	12.5	20	15	**30**	10	20	0	10	0	**13**	0	0	0	0	0	**0**	0	0
SY Kairo	12.5	22.5	15	**35**	10	22.5	13	13	0	**15**	0	0	0	0	0	**0**	0	0
SY Unitop	12.5	22.5	15	**40**	10	17.5	0	0	0	**0**	0	0	0	0	0	**0**	0	0
Total	12.5	20	15	**30**	10	20	0	10	0	**10**	0	0	0	0	0	**0**	0	0

Table 3.4-11: Phytotoxicity results of 2 variety trials carried out in France in 2013

Trial:	7980-FR-13-SEL-POST-MA / IIIA 6.2.1/116 (Mediterranean)	7980-FR-13-SEL-POST-MA / IIIA 6.2.1/117 (Maritime)
Cultivars:	Adrexxo, AY Miami, DKC5007, DKC5830, DKC6130, Exxclam, Exxclusiv, Kimberler, LG3385, LG3490, Mas 37 V, Memoxx, Onexx, Oxxygen, P0725, P9838, Phileaxx, PR33Y74, PR38N86, Texxel	Adevey, Dorelli, Equilibro, Joliet, Koherens, Laperi CS, Luigi CS, MAS 1, MAS 2, MAS 3, MAS 4, Millesim, SY Milkitop, SY Plentude, SY Trusteo, SY Unitop, Tessali CS
Result:	All cultivars: - No phytotoxicity	All cultivars: - No phytotoxicity - At GS >49 BBCH: Delay of development: A18385B – 0.5 kg/ha: 10 % A18385B – 1.0 kg/ha: 20 % Banvel 4S – 2X rate: 0 %

Summary and conclusions

In a total of 26 trials (21 of them with the double rate included and carried out under almost weed free conditions and 5 of them carried out as variety trials), it was shown that A18385B does not cause a substantial risk for the treated crop when applied at the target rates of 0.5 kg/ha (+ adjuvant). Occasionally occurring adverse effects do not cause reductions in yield. However to further minimize any risk, it is recommended to apply the product on actively growing dry crops and avoid applications in any crop stress situation. In overlapping areas, there is a slightly higher but still acceptable risk of phytotoxicity. There are no indications of varietal sensitivity of maize to A18385B.

Comments of zRMS:	The applicant tested phytotoxicity in 35 effectiveness trials at dose rate 0,4 L/ha and 0,5 L/ha. Additionally the phytotoxicity was tested in 19 selectivity trials (a report nr PLWEZH1012015 was not submitted) with 1N and 2N dose rate (0,4 L/ha; 0,8 L/ha L and 0,5 L/ha; 1,0 L/ha). Phytotoxicity symptoms in the range of maximum >5 to 15% were observed in 5 efficacy trials (CZKJZH1052015, DEMVZH9112013, PLFPZH1132013, PLUPOH1052012, DESEZH4432013). In two trials symptoms appeared transient whereas in 3 trials phytotoxicity symptoms maintained 41-58 DAA in the range ≤ 10%. Reference products behaved in similar way. Selective trials were carried out (in CZ, PL and DE) on following varieties of maize (BBCH: 13-17): LG 32.58, Ciclixx, Ricadinio, PR39F58, San, Libreto, P7524, PR39D23, P8000, Geoxx, DS0553, SYKardona, MAS22R, Simao, MAS25D< Ronaldinio, Colisee. Phytotoxicity symptoms were observed in 4 trials. In one trial symptoms appeared transient. In three trials deformation, discoloration, hight reduction, stunning or lower vigor were observed to the end of assessment. The maximum assessed effects were ≤ 10% for dose rate 1N (0,4 L/ha or 0,5 L/ha). Simultaneously, yield was not reduced significantly in those trials. What is more in two trials - one efficacy trial and one selectivity trial where one variety of maize – San was tested, adverse effects were observed. To check tolerance of different cultivars of maize, the Applicant presented 3 trials caried out in DE (reports of French trials was not submitted). The following cultivars of maize were tested: Maseto, SYUnitop, SYKairo, NK Falkone, Sherley, DKC3490, DKC 3307, Susann, Atletico, Fernandez, P800, Total, Saludo, ES Prolog, LG3220 Logo. In one trial no phytotoxicity symptoms were observed. In the second one on 10 cultivars (SYKairo, NK Falkone, Sherley, DKC 3307, Susann, Atletico, P800, Total, Saludo, ES Prolog) transient chlorosis were observed. In the third trial on each tested cultivars stunning was observed. Adverse effects decreased on 48 DAA – for dose rates 04, L/ha and 0,8 L/ha stunning disappeared, for dose rate 0,5 L/ha it was at the level 10 %. For the dose rate 2N adverse effect was at the higher level 12,5% – 17,5%. Important conclusion is also that no clear dose response has been observed. It might be assumed that there are no indications of varietal sensitivity of maize to A18385B. It might be concluded that adverse effects might appeared occasionally after the product application. They might be transient or long lasting and they should not cause

	reductions in yield. Nevertheless following the Applicant's proposition, information on applying the product on actively growing dry crops and avoid applications in any crop stress situation should be placed on the label.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

21 crop tolerance trials conducted yield quantity assessments. The objective was to confirm the absence of adverse effects on the yield quantity of maize following an application of A18385B. Results are presented from A18385B applied at the maximum intended rate of 0.5 kg/ha and the double rate of 1.0 kg/ha to simulate accidental spray overlap in post emergence between BBCH 12 and 18 of the crop. The yield was compared to the standard single and double rate, respectively.

Table 3.4-12: Summary of harvested weed free crop safety trials, separated by EPPO zone.

EPPO zone	EU zone	Country	Year			Sum
			2012	2013	2015	
Maritime	Central	CZ	2	3	-	5
		DE	3	5	-	8
	Sum		***5***	***8***	**-**	***13***
North-East	Central	PL	-	5	3	8
Total across EPPO zones			**5**	**13**	**3**	**21**

Materials and methods for the trials carried out on weed-free sites are described in Section 3.4.1

Summary tables show means of the grain yield quantity (in dt/ha) per EPPO zone. Data from the maritime EPPO zones are included in the overall mean as it was previously demonstrated that the performance of the product is uniform by the side comparisonin the efficacy section. The results are expressed as absolute values and as relative values compared to the untreated controls (=100%).

Overall summary of the effects on yield (quantity)

At the recommended and also at higher application rates the formulation does not have a negative treatment related impact on the harvested grain yield quantity nor on the forage weight.

An overall summary over the weed free selectivity trials, where measurements of crop yield and forage were carried out are shown in the **Table 3.2-14** and **Table 3.4-14** below.

In most trials, differences between treatments or between treatments and untreated control were not statistically significant. Yield responses were also not dosage related. Therefore, it can be concluded that differences in yield measurements in individual trials are due to the inherent experimental variation and are not treatment related. Thus, the data can be considered as supportive evidence of the good crop safety of the test product.

The trials where crop injury led to yield reductions can be considered exceptional:

In one Polish trial (PLUPZH1412013) the lower grain yield of the plots treated with 0.8 kg/ha A18385B is not considered being related to the product, since in the same trial the yield achieved on plots treated with 1.0 kg/ha A18385B is equal to the yield achieved from untreated plots.

In one German trial (7980-DE-13-SEL-MA_tr2) the double rate of A18385B caused a significantly lower yield of forage maize (whole plant weight). In this trial the yield reduction is clearly correlated to growth inhibition (35 %) observed for this treatment. However, at the 1N dose rate of 0.5 kg/ha no yield reduction was observed in this trial.

Significant but transient initial phytotoxicity observed in some other trials (please refer to section 3.4.1) had also no negative impact on maize yield.

Table 3.4-13: Summary of grain yield data in maize in absence of weeds (mean yield relative to control)

EPPO Zone	N° of trials	Yield (% relative to untreated)											
		A18385B (CHA 7980) + adjuvant								Reference products			
		0.4 kg/ha		2 x 0.4 kg/ha		0.5 kg/ha		2 x 0.5 kg/ha		X rate		2X rate	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range
Maritime	5	104	98-107	101	94-106	-	-	-	-	101	95-107	97	93-102
	4	104	98-107	101	94-106	98	95-103	99	92-104	101	95-107	96	93-100
North-East	4	97	91-101	96	86-101	102	95-107	99	98-102	97	91-107	98	90-105
	7	-	-	-	-	102	95-107	98	85-106	99	91-107	100	93-115
Across EPPO zones	***9***	***100***	***91-107***	***99***	***86-106***	**-**	**-**	**-**	**-**	***99***	***91-107***	***97***	***90-105***
	11	**-**	**-**	**-**	**-**	***100***	***95-112***	***99***	***92-106***	***100***	***91-107***	***99***	***90-115***

Table 3.4-14: Summary of forage weight data in maize in absence of weeds (mean yield relative to control)

EPPO Zone Maritime	N° of trials	Yield (% relative to untreated)											
		A18385B (CHA 7980) + adjuvant								Reference products			
		0.4 kg/ha		2 x 0.4 kg/ha		0.5 kg/ha		2 x 0.5 kg/ha		X rate		2X rate	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range	Mean	Range
Fresh weight	3	**97.3**	96-98	**95.3**	86-102	-	-	-	-	**104.0**	102-105	**99.0**	98-100
	2	**98.0**	98-98	**100.0**	98-102	**96.5**	96-97	**99.5**	99-100	**103.5**	102-105	**99.0**	98-100
Dry weight	5	**102.8**	99-106	**99.8**	77-119	**99.6**	85-114	**98.2**	76-116	**96.8**	89-104	**98.4**	77-112

Conclusion

A18385B applied at the intended target dose rate of 0.5 kg/ha or the double dose rate do not cause any reductions in yield or quality of maize grown for grain or silage.

Comments of zRMS:	A18385B was considered as safe to maize when used according to the GAPs. That is why no negative impact is expected on yield when A18385B is applied according to the claimed GAP.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

In 21 weed free selectivity trials yield quality measurements were carried out. In this section yield quality measurements such as:

Grain:

- Moisture content, thousand grain weight, protein content, starch content, crude fat content, crude ash content, crude fibre content;

Whole plants (forage maize):

- Starch content, crude protein content, crude fibre content, crude ash content, content of net-energy-lactation, content of net-energy of gain, content of energetic digestible protein, content of nitrogen digestible

carried out in maize are summarized.

The test product was mostly applied at 0.5 kg/ha (single application rate) and at 1.0 kg/ha (double application rate). In each trial the test product at the single and at the double recommended application rates was compared to a reference standard. The reference products were also applied at their single and double recommended application rates.

Summary tables show means of the different yield quality measurements per EPPO zone in separate lines. In addition – if appropriate – a mean over all EPPO zones was calculated. These weighted averages across a range of trials within the same EPPO zone are considered especially relevant and are highlighted in grey. The results are expressed as absolute values and as relative values compared to the untreated controls (=100%).

Materials and methods for the trials carried out on weed-free sites are described in Section 3.4.1

Overall summary of yield quality measurements in maize

The results clearly demonstrate that a treatment with A18385B at the intended target rates does not cause any deterioration of the quality of maize grain yield. Even the application of the double rate does not cause any substantial risk for the quality of the grain yield. There are no differences between the two EPPO zones. In most trials differences between treatments or between treatments and untreated control were not statistically significant.

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 has no negative effect on the different yield quality parameters measured in maize crops.

A summary table containing the results from maize with the means over all EPPO zones is shown in Table 3.4-14 to table 3.4-20 below.

Table 3.4-15: Moisture content of grains

EPPO zone		# of trials	Untrt.	A18385B + adjuvant				RefP	
			[% H_2O]	0.4 kg/ha	0.8 kg/ha	0.5 kg/ha	1.0 kg/ha	X rate	2X rate
				Moisture content relative to control					
Maritime	*Mean*	*5*	*31.9*	*99*	*99*	*-*	*-*	*98*	*100*
	Mean	***4***	***30.2***	***100***	***100***	***99***	***98***	***99***	***100***
North-East	*Mean*	*4*	*35*	*98*	*100*	*100*	*98*	*99*	*99*
	Mean	***7***	***31.4***	***-***	***-***	***97.1***	***97.1***	***98.0***	***97.9***
Mean across zones		11	***31.5***	***-***	***-***	***98.1***	***97.7***	***98.3***	***99.0***

RefP : Banvel 4 S or equivalent dicamba products

Table 3.4-16: Thousand grain weight

EPPO zone		# of trials	Untrt.	A18385B + adjuvant				RefP	
				0.4 kg/ha	0.8 kg/ha	0.5 kg/ha	1.0 kg/ha	X rate	2X rate
			[g]	TGW relative to control					
Maritime	***Mean***	***3***	***301.7***	***102***	***102***	***101***	***105***	***103***	***101***
North-East	*Mean*	*4*	*333.7*	*99*	*99*	*100*	*99*	*99*	*98*
	Mean	***7***	***320.3***	***-***	***-***	***101.1***	***99.3***	***101.7***	***100.0***
Mean across zones		10	***313.6***	***-***	***-***	***101.1***	***101.5***	***102.2***	***100.6***

RefP : Banvel 4 S or equivalent dicamba products

Table 3.4-17: Protein content of grains

EPPO zone		# of trials	Untrt.	A18385B + adjuvant				RefP	
				0.4 kg/ha	0.8 kg/ha	0.5 kg/ha	1.0 kg/ha	X rate	2X rate
			[%]	% Protein content relative to control					
Maritime	***Mean***	***2***	***9.0***	***108***	***101***	***98***	***112***	***105***	***102***
	Mean	*3*	*8.0*	*107*	*106*	*106*	*113*	*102*	*103*
North-East	***Mean***	***6***	***8.7***	***-***	***-***	***104***	***107***	***101***	***102***
Mean across zones		8	***8.8***	***-***	***-***	***102***	***109***	***103***	***102***

RefP : Banvel 4 S or equivalent dicamba products

Table 3.4-18: Starch content of grains

EPPO zone		# of trials	Untrt.	A18385B + adjuvant				RefP	
				0.4 kg/ha	0.8 kg/ha	0.5 kg/ha	1.0 kg/ha	X rate	2X rate
			[%]	% Starch content relative to control					
Maritime	***Mean***	***2***	***70.4***	***100.5***	***100.7***	***101.9***	***99.3***	***100.9***	***101.2***
	Mean	*3*	*66.2*	*99.0*	*99.0*	*99.3*	*98.0*	*99.7*	*99.3*
North-East	***Mean***	***6***	***66.2***	***-***	***-***	***99.7***	***98.5***	***99.7***	***99.3***
Mean across zones		8	***67.6***	***-***	***-***	***100.4***	***98.7***	***100.1***	***100.0***

RefP : Banvel 4 S or equivalent dicamba products

Table 3.4-19: Crude fat content of grains

EPPO zone		# of trials	Untrt.	A18385B (CHA 7980) + adjuvant				RefP	
				0.4 kg/ha	0.8 kg/ha	0.5 kg/ha	1.0 kg/ha	X rate	2X rate
			[%]	% Crude fat content relative to control					
Maritime	*Mean*	*2*	*4.3*	*101*	*101*	*102*	*99*	*101*	*101*
North-East	*Mean*	*3*	*4.0*	*99*	*99*	*99*	*98*	*100*	*99*
	Mean	*6*	*4.0*	*-*	*-*	*94.2*	*96.2*	*95.0*	*95.5*
Mean across zones		*8*	*4.1*	*-*	*-*	*96.8*	*97.1*	*97.0*	*97.4*

RefP : Banvel 4 S or equivalent dicamba products

Table 3.4-20: Crude ash content of grains

EPPO zone		# of trials	Untrt.	A18385B (CHA 7980) + adjuvant				RefP	
				0.4 kg/ha	0.8 kg/ha	0.5 kg/ha	1.0 kg/ha	X rate	2X rate
			[%]	Crude ash content relative to control					
Maritime	*Mean*	*2*	*1.1*	*98*	*94*	*105*	*103*	*102*	*95*
North-East	*Mean*	*3*	*1.3*	*101*	*97*	*100*	*99*	*99*	*97*
	Mean	*6*	*1.3*	*-*	*-*	*100.3*	*100.4*	*100.4*	*97.3*
Mean across zones		8	*1.3*	*-*	*-*	*101.7*	*101.0*	*100.8*	*96.6*

RefP : Banvel 4 S or equivalent dicamba products

Table 3.4-21: Crude fibre content of grains

EPPO zone		# of trials	Untrt.	A18385B (CHA 7980) + adjuvant				RefP	
				0.4 kg/ha	0.8 kg/ha	0.5 kg/ha	1.0 kg/ha	X rate	2X rate
			[%]	Crude fibre content relative to control					
Maritime	*Mean*	*2*	*3.0*	*100*	*65*	*73*	*94*	*68*	*60*
North-East	*Mean*	*3*	*1.8*	*98*	*102*	*100*	*99*	*96*	*89*
	Mean	*6*	*4.7*	*-*	*-*	*97.7*	*99.0*	*99.7*	*97.7*
Mean across zones		8	*4.2*	*-*	*-*	*89.8*	*96.9*	*89.8*	*85.6*

RefP : Banvel 4 S or equivalent dicamba products

In Table 3.4-22 below the results of the analysis of quality parameters of the whole maize plants (forage maize) are presented. They clearly demonstrate that a treatment with A18385B at the intended target rate does not cause any deterioration of the quality of forage maize. Even the application of the double rate does not cause any substantial risk for the quality of maize plants being assigned for forage. A trend of seemingly lower starch contents cannot be related to A18385B, since this effect can be observed for all products independent of the rate applied. Quality results for forage maize have been conducted in Germany and Czech Republic of the Maritime EPPO zone only.

Table 3.4-22: Quality properties (relative to control) based on dry mass of forage maize in EPPO zone Maritime

Quality para-meter		# of trials	Untrt.	A18385B (CHA 7980) + adjuvant				RefP	
				0.4 kg/ha	0.8 kg/ha	0.5 kg/ha	1.0 kg/ha	X rate	2X rate
			[abs]	relative to control					
Starch content [% DM]	***Mean***	***6***	***31.7***	***84***	***88***	***90***	***87***	***85***	***94***
Crude protein content [% DM]	***Mean***	***5***	***7.4***	***101***	***101***	***99***	***104***	***103***	***100***
Crude fibre content [% DM]	***Mean***	***5***	***19.2***	***113***	***112***	***106***	***107***	***109***	***106***
Crude ash content [% DM]	***Mean***	***5***	***4.2***	***110***	***108***	***101***	***106***	***103***	***110***
Net-energy-lactation[mJ/kg]	***Mean***	***5***	***8.1***	***97***	***96***	***98***	***98***	***98***	***99***
Net-energy of gain[mJ/kg]	***Mean***	***5***	***7.2***	***98***	***94***	***96***	***101***	***96***	***98***
Energetic digest. Protein [‰ DM]	***Mean***	***5***	***218.1***	***111***	***112***	***104***	***109***	***109***	***102***
Digest. Nitrogen [‰ DM]	***Mean***	***3***	***58.0***	***100***	***98***	***102***	***103***	***101***	***102***

RefP : Banvel 4 S or equivalent dicamba products

Based on the results of 6 trials harvested for the yield of forage maize, the following can be concluded:

There are no indications for a negative impact on quality of plants and plant products in maize if A18385B is applied at the intended target dose rates. Even at the double rates there is no substantial risk for an impact on plant or plant products.

Comments of zRMS:	In 19 selectivity trials on maize the impact of A18385B on following quality parameters was investigated: • for grain: moisture content, thousand grain weight, protein content, starch content, crude fat content, crude ash content, crude fibre content. • for whole plants (forage maize): starch content, crude protein content, crude fibre content, crude ash content, content of net-energy-lactation, content of net-energy of gain, content of energetic digestible protein, content of nitrogen digestible. No significant differences were observed between the test product A18385B and the reference product Banvel 4S in quality parameters. No impact on quality of plants or plant products is to be expected after an application of A18385B if it is applied at the intended target dose rates.

3.4.4 Effects on transformation processes (KCP 6.4.4)

No processing studies were carried out on harvested maize sprayed with A18385B. Refer to Part B Section 7 for information on residues in harvested/processed parts of plant (residues were in line with MRLs).

Comments of zRMS:	The applicant gave the explanation that residues were in line with MRLs and no data on transformation process are required. The evaluator has accepted that explanation if residues in maize are assessed as acceptable.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

No trials were conducted to assess the germination of seed obtained from maize crops treated with A18385B. However as the crop is treated early in the season and no residues are found in the treated crop, it is very unlikely A18385B has any adverse effects on the germination of the treated crop seed.

Comments of zRMS:	The applicant gave the explanation that no residues are found in the treated crop and no data on impact on treated plants or plant products to be used for propagation are required. The evaluator has accepted that explanation (in line with the EPPO standard PP 1/135 Phytotoxicity assessment) if residues in maize grains are not detectable.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

With reference to EPPO guideline PP1 207(2), a risk analysis for an impact on succeeding crops was performed. As a first step TERs were calculated for nicosulfuron and prosulfuron to determine the risk for succeeding crops with different time intervals after application. The calculation is based on the results of EC_{10} values which were determined with representative straight-formulated products for a range of crop species in bioassays for the determination of their sensitivity to soil residues of nicosulfuron and prosulfuron and the PEC_{soil} values (DT_{50} nicosulfuron = 63 days [worst case field]; DT_{50} prosulfuron = 36 days [worst case fields]) of these active substances under consideration of different time intervals after application. Due to its degradation behaviour (DT_{50} = 4 days), dicamba can be neglected for this risk estimation.

TER calculations

Based on the different scenarios for PEC_{soil} calculations, the TERs were calculated separately for nicosulfuron and prosulfuron for different soil cultivation situations (shallow [5 cm mixing depth in soil] and deep [20 cm mixing depth in soil] cultivation) and an interception = 25 % (post-emergence conditions).

The calculations show for **prosulfuron** that under the conditions of shallow soil cultivation, the monocotyledonous crops sorghum, maize and winter wheat reached the critical TER of ‘1’ within a time frame of 7 days after application. This indicates that no unacceptable risk for these succeeding crops is expected, even in case of early replanting due to a crop failure.

Oilseed rape and pea reach the critical TER within a time frame of 21 to 50 days, while the critical TER is reached not earlier than about 200 days after application by the most sensitive crops sugar beet and sunflower.

After deep soil cultivation (ploughing), oilseed rape and peas may be planted as replacement crops as they reached the critical TER within a time frame of 7 days. However sugar beet and sunflower still needed 100 to 200 days to reach this value and can be used only as following crops in a normal crop rotation.

The calculations show for **nicosulfuron** that under the conditions of the shallow soil cultivation, maize, sunflower and pea reached the critical TER of '1' within a time frame of 7 to 14 days after application. This indicates that no unacceptable risk for these succeeding crops is expected, even in case of early replanting due to a crop failure.

Oilseed rape and sugar beet appear to show a difference in their varietal sensitivity to nicosulfuron. Oilseed rape, sugar beet, winter wheat, rye grass and sorghum needed 100 to 200 days to reach the critical TER. A deep cultivation (ploughing) performed prior to sowing may secure the crop safety of oilseed rape, winter wheat and rye grass (critical TER reached within a time frame of 7 to 14 days), but doesn't allow to sow sorghum or sugar beet to be grown as replacement crops.

Conclusion

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.

Comments of zRMS:	Considering presented calculations the only safe cultivation at early sowing is maize. After deep soil cultivation (ploughing) peas, oilseed rape, winter wheat and rye grass may be sown as replacement crops beyond 14 days after application. What is more for oilseed rape, winter wheat and rye grass sown in the early autumn, a deep soil cultivation is recommended to secure the crop safety.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

A18385B is intended for application to cereal varieties between BBCH 13 and 18 and therefore the number of adjacent crops which may be exposed to drift and/or vapour action is considerable. The threat posed by A18385B is deduced using its TER values, with a value lower than 1 indicating a risk to adjacent crops. Reference is made to **Part B Section 9 (Ecotoxicology)** *Effects on non-target terrestrial plants* (KCP 10.6) where studies have been performed investigating the effects of A18385B on non-target plants with a summary provided below for the readers convenience. The text has been partially modified with further explanations to describe the impact of A18385B to adjacent crops.

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, and the maximum off-field predicted environmental residues (PERs).

For the seedling emergence risk assessment the TER was less than the trigger value indicating an unacceptable pre-emergence risk from A18385B to non-target plants, therefore mitigation is required.

For the vegetative vigour risk assessment the TER was less than the trigger indicating an unacceptable post-emergence risk from A18385B to non-target plants. A higher tier refinement of the ecological endpoint (SSD approach) indicates unacceptable risk and therefore mitigation is required.

The risk to non-target terrestrial plants in off-crop areas is acceptable following use of A18385B according to the proposed use pattern, when the following mitigations are applied.

1 x 400 g A18385B/ha:
- No buffer and 90% drift reduction mitigation or
- 5 m buffer with 50% drift reduction or
- 10 m buffer with no drift reduction

1 x 500 g A18385B/ha:
- 5 m buffer with 75% drift reduction or
- 10 m buffer with 50% drift reduction or
- 15 m buffer with no drift reduction.

When based on the most sensitive ER_{50} 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

Comments of zRMS:	The Applicant used the most sensitive ER_{50} (new endpoints) of the higher tier field studies to assess risk to non-target terrestrial plants in off-crop areas. Use of A18385B should be safe for non-target terrestrial plants in off-crop areas if the following mitigation is implemented: • 5m buffer or • 1 m buffer with using 90% drift-reducing nozzles

Tank cleaning

As A18385B contains active substances that may cause severe injury to sensitive crops when residues are not washed off previously, tests have been carried out to determine the effectiveness of the tank cleaning procedure for A18385B (in mixture with ADIGOR). For details refer to Part B Section 1.

Based on the Section 1 statement, the following label recommendation is proposed to be strictly followed:

1. *Immediately after spraying, drain tank completely. Any contamination on the outside of the spraying equipment should be removed by washing with clean water.*
2. *Rinse inside of tank with clean water and flush through the spray boom and hoses for several minutes. Drain again completely.*
3. *Fill at least 1/4 of the tank with clean water and add 1 litre household ammonia (containing minimum 3% ammonia) per 100 litres of water. Agitate and circulate the cleaning solution through the boom and hoses; then allow to stand for at least 15 minutes with agitation. Drain tank completely.*
4. *Repeat steps 2 and 3 once again.*
5. *Remove nozzles and filters and clean separately with the cleaning solution at the same concentration as above.*

There is no evidence that alkaline sprayer cleaners commercially available to remove herbicide deposits, especially sulfonylurea deposits (e.g. All Clear Extra), used at their recommended rate, are not efficient as well for cleaning application equipment after spraying A18385B.

Comments of zRMS:	The Applicant proposed procedure for tank cleaning which should be efficient for cleaning application equipment after spraying A18385B.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in **Part B Section 9 Ecotoxicology** under KCP 10.3.2 and 10.5. For the readers convenience an extract of the summary conclusions is provided below in order to demonstrate the safety of A18385B to beneficial and other non-target organisms encountered in crop situations where the product will be used:

" 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 accord-ing to the proposed use pattern."

Soil meso- and macrofauna
" 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 PECsoil values. All acute and chronic TER values are greater than the Regulation (EU) 546/2011 triggers of 10 and 5, respective-ly, 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 PECsoil. The TERLT 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."

Soil micro-organisms
" The risk of A18385B, prosulfuron, nicosulfuron, dicamba and relevant metabolites to soil micro-organisms was evaluated by comparison of the maximum concentrations with effects <25% de-rived from laboratory tests, with maximum PECsoil. All the effect levels exceeded the relevant PECsoil values, indicating that the risk to soil micro-organisms is acceptable following the use of A18385B according to the proposed use pattern. "

Based on the information provided in Part B Section 9 and no adverse effects observed in field trials, A18385B is indicated to be safe to beneficial and other non-target organisms.

Comments of zRMS:	Negative effects on beneficial and other non-target organisms were not observed in the efficacy trials.

Summary and conclusion

All crops can be planted without restrictions in the normal crop rotation. However, in case of early recultivation due to crop failure it is recommended to plant 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.

As for all herbicides, appropriate measures to avoid spray drift to adjacent crops should be taken. It is recommended to use drift reducing nozzles when applying A18385B.

To avoid residues of the herbicide in the spray tank after application of the product appropriate tank cleaning procedures are required. It is recommended to repeatedly rinse the spary tank with fresh water preferably together with an appropriate tank cleaning product.

Based on the studies available and based on practical experience from commercial use A18385B is safe to beneficials and other non-target organisms.

3.6 Other/special studies (KCP 6.6)

Not submitted.

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials were done. All facilities are certified and the trials conducted according to GEP.

The corresponding certificates are available in the GEP Certificate Database System (Certibase) (http://www.gepcertibase.eu) via the hyperlinks provided in the table below.

Table 3.7-1: List of test facilities

Hyperlink to certificate	Test facility	Country	Address	Number of trials			
				2012	2013	2014	2015
1d4eedc51a8	Crop Research Institute Prague	Czech Republic	Drnovská 507 161 06 Praha 6	2	1	-	-
1d4eedc5209	Czech Agricultural University	Czech Republic	Kamýcká 129 165 21 Praha 6	1	2	2	-
1d4eedc4ed7	Zemedelska ZC Kujavy	Czech Republic	Kujavy 48 724 44 Kujavy	-	2	-	-
1d4eedc4ede	ZS Nechanice, s.r.o	Czech Republic	Štolbova 319 503 15 Nechanice	2	2	-	-
1d4eedc4f71	BioChem Agrar	Germany	Kupferstraße 6 04827 Gerichshain	5	6	-	-
1d656c0e6ad	BioChem Agrar	Poland	Urbanowice, Kozielska 48 47-260 Polska	-	-	-	3
1d4eedc5338	Eurofins Agroscience Services GmbH	Germany	Carl Goerdeler Weg 5 21684 Stade	2	-	-	-
1d4eedc4fad	Syngenta Agro GmbH	Germany	Am Technologiepark 1-5 63477 Maintal	5	7	-	-
1d4eedc506a	Field Research Support	Poland	Ul.Dworcowa 2 64-000 Koscian	-	4	-	1
1d4eff38ce2	Institute Ochrony Roslin	Poland	Ul.Gliwicka 29 44-153 Sosnicowice	-	2	-	-
1d4eedc507a	Uniwersytet Przyrodniczy ZDD Gorzyn	Poland	Ul. Mazowiecka 45/46 60-623 Poznan	-	3	1	2
1d656c0e530	IPP-NRI Sosnicowice Branch	Poland	Gliwicka 29, 44-153 Sosnicowice	-	-	1	1
1d656c0e6f4	Syngenta Polska Sp. z o.o.	Poland	Powazkoska 44 C, 01-797 Warszawa	-	-	-	1
			TOTAL	18	29	4	8

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6	Richard Beyer	09/01/2020	Biological Assessment Dossier A18385B Syngenta Document No.VV-870123 non GEP Unpublished	N	SYN
Trial Reports					
KCP 6.1	Hilton, H.	31/12/2012	Field study to evaluate the efficacy of CHA7980 in tank mixture with different adjuvants, when applied post-emergence to maize for weed control Report No. 343 NIS (7980+ADJ-UK-EFF-13-POST-MA-01) Document No. VV-879597 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.1	Pardi, J.	31/12/2012	Field study to evaluate the efficacy of CHA7980 with different adjuvants when applied post-emergence to maize, 1 site in Hungary Report No. 369 NIS (S13-02909-01) Document No. VV-879600 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.1	Sentanes, J.	31/12/2013	Field study to evaluate the efficacy of CHA7980 in tank mixture with different adjuvants, when applied post-emergence to maize for weed control Report No. 340 NIS (CHE0913)	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Document No. VV-879596 Test Facility Syngenta, Ltd. GEP Unpublished		
KCP 6.2	Carstens, H.	17/12/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy Report No. DENOZH1602013 Document No. VV-861650 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.2	Kokoskova, D.	01/10/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZVPZH1042012 Document No. VV-861624 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.2	Siegert, E.	09/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. DEESZH3212012 Document No. VV-861626 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.2	Stanclova, L.	10/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZNEZH1012012 Document No. VV-861625	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Test Facility Syngenta GEP Unpublished		
KCP 6.3	Broz, M.	05/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. CZKJZH1052013 Document No. VV-861648 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Brunckhorst, G.	17/08/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. DEWEZH2352012 Document No. VV-861620 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Drzewiecki, S.	02/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. PLSOZH1272013 Document No. VV-861646 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Drzewiecki, S.	28/07/2014	A18385 B (WG54%- DIC/NSU/PSU) - Post-emergent broad-spectrum weed control by new premixture - 3d year Efficacy Report No. PLSO0H1122014 Document No. VV-861654 Test Facility Syngenta	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			GEP Unpublished		
KCP 6.3	Drzewiecki, S.	14/08/2015	A15901A (CALARIS PRO, MST+TBA) in Corn - Efficacy - GEP trials Report No. PLSOZH1052015 Document No. VV-861662 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Ehrenschwender, G.	30/08/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. DESEZH4412012 Document No. VV-861622 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Ehrenschwender, G.	22/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy Report No. DESEZH4432013 Document No. VV-861649 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Griehl, T.	14/09/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. DEOSZH3662012 Document No. VV-861621 Test Facility Syngenta GEP Unpublished	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6.3	Griehl, T.	21/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy Report No. DEOSZH3442013 Document No. VV-861652 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Griehl, T.	22/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy Report No. DEOSZH3662013 Document No. VV-861639 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Kokoskova, D.	13/08/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZVPZH1052012 Document No. VV-861618 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Kokoskova, D.	08/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. CZVPZH1042013 Document No. VV-861644 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Kroehnke, J.	31/08/2015	A15901A (CALARIS PRO, MST+TBA) in Corn - Efficacy - GEP trials	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Report No. PLNWZH1012015 Document No. VV-861666 Test Facility Syngenta GEP Unpublished		
KCP 6.3	Krueger, D.	25/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy Report No. DEMVZH9112013 Document No. VV-861651 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Maass, P.	31/12/2012	Field study to evaluate the efficacy of CHA7980 + Adigor and CHA7950 + Actirob B when applied post-emergence to maize for the control of weeds Report No. 270 NIS Document No. VV-879604 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.3	Maass, P.	31/12/2012	Field study to evaluate the efficacy of CHA7980 + Adigor and CHA7950 + Actirob B when applied post-emergence to maize for the control of weeds Report No. 271 NIS (S12-00993-03) Document No. VV-879605 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.3	Nitzsche, H.	31/12/2013	Field study to evaluate the efficacy of CHA7980 + Adigor, when applied post-emergence to maize for the control of weeds Report No. 327 NIS (7980-DE-13-EFF-Post_MA_tr3)	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Document No. VV-879594 Test Facility Syngenta, Ltd. GEP Unpublished		
KCP 6.3	Schmitt, B.	31/12/2013	Field study to evaluate the efficacy of CHA7980 + Adigor, when applied post-emergence to maize for the control of weeds Report No. 328 NIS (7980-DE-13-EFF-Post_MA_tr4) Document No. VV-879595 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.3	Skrzypczak, W.	27/07/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. PLUPZH1392013 Document No. VV-861647 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Skrzypczak, W.	27/07/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. PLUPZH1402013 Document No. VV-861641 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Skrzypczak, W.	28/07/2014	A18385 B (WG54%- DIC/NSU/PSU) - Post-emergent broad-spectrum weed control by new premixture - 3d year Efficacy Report No. PLUP0H1122014 Document No. VV-861653	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Test Facility Syngenta GEP Unpublished		
KCP 6.3	Slowiak, K.	08/09/2015	A15901A (CALARIS PRO, MST+TBA) in Corn - Efficacy - GEP trials Report No. PLWEZH0032015 Document No. VV-861665 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Sobiech, L.	04/08/2015	A15901A (CALARIS PRO, MST+TBA) in Corn - Efficacy - GEP trials Report No. PLUPZH1052015 Document No. VV-861663 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Soukup, J.	09/08/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZCPZH1032012 Document No. VV-861619 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Soukup, J.	05/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. CZCPZH1032013 Document No. VV-861640 Test Facility Syngenta GEP Unpublished	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6.3	Soukup, J.	22/07/2014	A18385 B (WG54%- DIC/NSU/PSU) - Post-emergent broad-spectrum weed control by new premixture - 3d year Efficacy Report No. CZCP0H1012014 Document No. VV-861655 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Soukup, J.	22/07/2014	A18385 B (WG54%- DIC/NSU/PSU) - Post-emergent broad-spectrum weed control by new premixture - 3d year Efficacy Report No. CZCP0H1022014 Document No. VV-861656 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Soukup, J.	05/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. CZCPZH1032013 Document No. VV-861640 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Mecklenburg-Vorpommern (Deutschland) Report No. N/A Document No. VV-877787 Test Facility N/A Not GLP Published	N/A	SYN
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Sachsen-Anhalt (Deutschland)	N/A	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Report No. N/A Document No. VV-877788 Test Facility N/A Not GLP Published		
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Unterfranken (Deutschland) Report No. N/A Document No. VV-877789 Test Facility N/A Not GLP Published	N/A	SYN
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Hannover (Deutschland) Report No. N/A Document No. VV-877784 Test Facility N/A Not GLP Published	N/A	SYN
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Lüneburg (Deutschland) Report No. N/A Document No. VV-877785 Test Facility N/A Not GLP Published	N/A	SYN
KCP 6.3	Sowinski, G.	28/10/2020	Report on comparison of regions: Wielkopolskie (Polska) and Warminsko-Mazurskie (Polska) Report No. N/A Document No. VV-877786 Test Facility N/A Not GLP Published	N/A	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6.3	Stanclova, L.	31/07/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZNEZH1022012 Document No. VV-861617 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Stanclova, L.	16/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. CZNEZH1052013 Document No. VV-861643 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Thiel, M.	31/12/2013	Field study to evaluate the efficacy of CHA7980 + Adigor, when applied post-emergence to maize for the control of weeds Report No. 325 NIS (7980-DE-13-EFF-Post_MA_tr1) Document No. VV-879592 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.3	Uminski, P.	02/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. PLFPZH1122013 Document No. VV-861645 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Uminski, P.	05/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			new premixture - 2d year Efficacy Report No. PLFPZH1132013 Document No. VV-861642 Test Facility Syngenta GEP Unpublished		
KCP 6.3	Uminski, P.	29/07/2015	A15901A (CALARIS PRO, MST+TBA) in Corn - Efficacy - GEP trials Report No. PLFPZH1042015 Document No. VV-861664 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.3	Weiss, E.	31/12/2012	Field study to evaluate the efficacy of CHA7980 + Adigor, when applied post-emergence to maize for the control of weeds Report No. 326 NIS (7980-DE-13-EFF-Post_MA_tr2) Document No. VV-879593 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.4	Broz, M.	15/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZKJZH1062013 Document No. VV-861630 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4	Drzewiecki, S.	19/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLSOZH1282013	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Document No. VV-861635 Test Facility Syngenta GEP Unpublished		
KCP 6.4	Hohnschild, J.	31/12/2012	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 302 NIS (7980-12-DE...SEL-POST-MA TR2) Document No. VV-879591 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.4	Kokoskova, D.	01/10/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZVPZH1042012 Document No. VV-861624 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4	Kolditz, M.	31/12/2013	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 347 NIS (7980-DE-13-SEL-MA_tr1) Document No. VV-879598 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.4	Kroehnke, J.	18/10/2015	A15901A (CALARIS PRO, MST/TBA) in Corn - Crop Tolerance - GEP trials Report No. PLBCZH1512015 Document No. VV-861659 Test Facility Syngenta GEP Unpublished	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6.4	Merz, D.	10/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. DESWZH5222012 Document No. VV-861627 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4	Scharf, H.	31/12/2013	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 348 NIS (7980-DE-13-SEL-MA_tr2) Document No. VV-879599 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.4	Siegert, E.	09/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. DEESZH3212012 Document No. VV-861626 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4	Sobieszczanski, R.	30/10/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLUPZH1412013 Document No. VV-861634 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4	Solarska, E.	04/12/2015	A15901A (CALARIS PRO, MST/TBA) in Corn - Crop Tolerance - GEP trials Report No. PLULZH1012015	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Document No. VV-861661 Test Facility Syngenta GEP Unpublished		
KCP 6.4	Soukup, J.	29/10/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZCPZH1042013 Document No. VV-861633 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4	Stanclova, L.	10/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZNEZH1012012 Document No. VV-861625 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4	Stanclova, L.	10/02/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZNEZH1062013 Document No. VV-861631 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4	Stuebner, B.	27/01/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. DEESZH3892013 Document No. VV-861637	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Test Facility Syngenta GEP Unpublished		
KCP 6.4	Stuebner, B.	27/01/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. DEESZH3902013 Document No. VV-861636 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4	Thiel, M.	31/12/2012	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 301 NIS (7980-12-DE...SEL-POST-MA TR1) Document No. VV-879590 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.4	Uminski, P.	20/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLFPZH1142013 Document No. VV-861628 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4	Uminski, P.	20/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLFPZH1152013 Document No. VV-861632 Test Facility Syngenta GEP	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Unpublished		
KCP 6.4.1	Carstens, H.	17/12/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergence broad-spectrum weed control by new premixture - 2nd year Efficacy Report No. DENOZH1602013 Document No. VV-861650 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.1	Hintz, C.	31/12/2012	Field study to evaluate the selectivity of CHA7950 and CHA7980 when applied post-emergence on different maize varieties Report No. 261 NIS (7950 + 7980 VAR trial 2) Document No. VV-879602 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.4.1	Thiel, M.	31/12/2012	Field study to evaluate the selectivity of CHA7950 and CHA7980 when applied post-emergence on different maize varieties Report No. 262 NIS (7950 + 7980 VAR trial 3) Document No. VV-879603 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.4.1	Uminski, P.	05/08/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum weed control by new premixture - 2d year Efficacy Report No. PLFPZH1132013 Document No. VV-861642 Test Facility Syngenta GEP Unpublished	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6.4.1	Wetzig, I.	31/12/2012	Field study to evaluate the selectivity of CHA7950 and CHA7980 when applied post-emergence on different maize varieties Report No. 260 NIS (7950 + 7980 VAR trial 1) Document No. VV-879601 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.4.2	Broz, M.	15/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZKJZH1062013 Document No. VV-861630 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Drzewiecki, S.	19/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLSOZH1282013 Document No. VV-861635 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Hohnschild, J.	31/12/2012	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 302 NIS (7980-12-DE...SEL-POST-MA TR2) Document No. VV-879591 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.4.2	Kokoskova, D.	01/10/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Report No. CZVPZH1042012 Document No. VV-861624 Test Facility Syngenta GEP Unpublished		
KCP 6.4.2	Kolditz, M.	31/12/2013	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 347 NIS (7980-DE-13-SEL-MA_tr1) Document No. VV-879598 Test Facility Syngenta, Ltd. GEP Unpublished	N	SYN
KCP 6.4.2	Kroehnke, J.	18/10/2015	A15901A (CALARIS PRO, MST/TBA) in Corn - Crop Tolerance - GEP trials Report No. PLBCZH1512015 Document No. VV-861659 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Merz, D.	10/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. DESWZH5222012 Document No. VV-861627 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Scharf, H.	31/12/2013	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 348 NIS (7980-DE-13-SEL-MA_tr2) Document No. VV-879599 Test Facility Syngenta, Ltd. GEP	N	SYN

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner SYN = Syngenta
			Unpublished		
KCP 6.4.2	Siegert, E.	09/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. DEESZH3212012 Document No. VV-861626 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Sobieszczanski, R.	30/10/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLUPZH1412013 Document No. VV-861634 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Solarska, E.	04/12/2015	A15901A (CALARIS PRO, MST/TBA) in Corn - Crop Tolerance - GEP trials Report No. PLULZH1012015 Document No. VV-861661 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Soukup, J.	29/10/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZCPZH1042013 Document No. VV-861633 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Stanclova, L.	10/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZNEZH1012012 Document No. VV-861625 Test Facility Syngenta GEP Unpublished		
KCP 6.4.2	Stanclova, L.	10/02/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZNEZH1062013 Document No. VV-861631 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Stuebner, B.	27/01/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. DEESZH3892013 Document No. VV-861637 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Stuebner, B.	27/01/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. DEESZH3902013 Document No. VV-861636 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Thiel, M.	31/12/2012	Field study to evaluate the selectivity of CHA7980 when applied post-emergence to maize Report No. 301 NIS (7980-12-DE...SEL-POST-MA TR1)	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Document No. VV-879590 Test Facility Syngenta, Ltd. GEP Unpublished		
KCP 6.4.2	Uminski, P.	20/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLFPZH1142013 Document No. VV-861628 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.2	Uminski, P.	20/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLFPZH1152013 Document No. VV-861632 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Broz, M.	15/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZKJZH1062013 Document No. VV-861630 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Drzewiecki, S.	19/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLSOZH1282013 Document No. VV-861635	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Test Facility Syngenta GEP Unpublished		
KCP 6.4.3	Kokoskova, D.	01/10/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZVPZH1042012 Document No. VV-861624 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Kroehnke, J.	18/10/2015	A15901A (CALARIS PRO, MST/TBA) in Corn - Crop Tolerance - GEP trials Report No. PLBCZH1512015 Document No. VV-861659 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Merz, D.	10/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. DESWZH5222012 Document No. VV-861627 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Siegert, E.	09/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. DEESZH3212012 Document No. VV-861626 Test Facility Syngenta GEP	N	SYN

Data point	Author(s)	Year	**Title** **Source** **Company Report No.** **GLP or GEP status** **Published or Unpublished** **Syngenta File No.**	Vertebrate study Y/N	Owner SYN = Syngenta
			Unpublished		
KCP 6.4.3	Sobieszczanski, R.	30/10/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLUPZH1412013 Document No. VV-861634 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Solarska, E.	04/12/2015	A15901A (CALARIS PRO, MST/TBA) in Corn - Crop Tolerance - GEP trials Report No. PLULZH1012015 Document No. VV-861661 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Soukup, J.	29/10/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZCPZH1042013 Document No. VV-861633 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Stanclova, L.	10/12/2012	A18385B - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture (18385 -WG- DIC/NSU/PSU) - 1st y registration trials Report No. CZNEZH1012012 Document No. VV-861625 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Stanclova, L.	10/02/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and	N	SYN

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			broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. CZNEZH1062013 Document No. VV-861631 Test Facility Syngenta GEP Unpublished		
KCP 6.4.3	Stuebner, B.	27/01/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. DEESZH3892013 Document No. VV-861637 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Stuebner, B.	27/01/2014	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. DEESZH3902013 Document No. VV-861636 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Uminski, P.	20/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance Report No. PLFPZH1142013 Document No. VV-861628 Test Facility Syngenta GEP Unpublished	N	SYN
KCP 6.4.3	Uminski, P.	20/11/2013	A18385B (WG54% - DIC/NSU/PSU) - CE & SE-EU - Post-emergent broad-spectrum (grasses and broadleaves) weed control by new premixture - 2d year Crop tolerance	N	SYN

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			Report No. PLFPZH1152013 Document No. VV-861632 Test Facility Syngenta GEP Unpublished		