

REGISTRATION REPORT
Part B Section 3
Efficacy Data and Information
Concise summary

Product code: AG-E1-500 SC1

Product name: Ethosat 500 SC

Chemical active substance:

Ethofumesate, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

North-East and South-East EPPO climatic zones
(new authorization)

Sponsor: ADAMA Agan Ltd.

Applicant: ADAMA Polska Sp. z o.o.

Submission date: March 2021

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June 2022 (final Core Assessment)

Version history

When	What
March 2021	Initial dRR - ADAMA
January 2022	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency .
June 2022	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded .

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

The draft Registration Report is a concise summary of the data submitted to support the Art 33 registration of the plant protection product AG-E1-500 SC1, a herbicide containing 500 g/L of ethofumesate (SC formulation) in the Central Regulatory zone countries – North-East and South-East EPPO zones, Poland, Hungary and Slovakia.

The intention of this document is to summarize the information of trials to support the use of AG-E1-500 SC1 for weed control in sugar beets and fodder beets (post-emergence applications).

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

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

Abstract

Abstract by zRMS

Introduction

AG-E1-500 SC1 is a formulation of a known active: ethofumesate, intended to control broadleaved weeds in sugar beet and fodder beet crops. Ethofumesate is currently in use in some European member states, in several solo products and in manufacturers' mixtures with another actives. The product being subject of the present submission had been previously authorized in a number of states of the Central Regulatory zone, but is currently not authorized. Therefore the objective of the application is to obtain new authorization for AG-E1-500 SC1, following the art. 33 of the 1107/2009.

AG-E1-500 SC1 is proposed to be used either in solo application (3*0.6 L/ha in Poland and 2*1.0 L/ha in Hungary and Slovakia), or in the tank-mix with Goltix Titan 565 SC, containing actives metamitron and quinmerac, accompanied by the plant oil – based adjuvant, in Poland.

Data

The main body of **efficacy** data consists of **23 trials**, all including lower dose rates in order to address the MED requirement, with 10 trials carried out in Poland (North-Eastern EPPO zone) and the remaining 13 – in Hungary (6) and Slovakia (7), supporting the South-Eastern zone. Additionally, 6 trials are submitted from the Maritime zone, from the Czech Republic (4) and Germany (2), which do not include lower dose rates. The Maritime zone trials are meant to support efficacy assessment for the key weed species targeted by AG-E1-500 SC1 in Poland, and to provide selectivity data. **Selectivity** data set includes altogether **18 field selectivity trials** (including 4 Maritime zone supportive trials) focused on phytotoxicity and yield, as well as **3 trials concerning succeeding and replacement crops**, including 1 laboratory trial. **Neither the efficacy nor the selectivity trials carried out in the Czech Republic and Germany can alone be considered sufficient to support the approval in the Maritime EPPO climatic zone. The MED data is missing from these trials, the overall frequency of individual weed species is too low and the number of the dedicated selectivity trials in the Maritime zone (4) is insufficient.**

Minimum Effective Dose

The dose rate of 3*0.6 L/ha should be considered as MED for Poland (the North-Eastern EPPO zone), whereas 2*1.0 L/ha should be the MED for Hungary and Slovakia (the South-Eastern EPPO zone).

Efficacy in the North-Eastern EPPO zone (Poland)

The following weed susceptibility is concluded after **solo application** of AG-E1-500 SC1 at the dose rate of 3*0.6 L/ha:

Highly susceptible	STEME
Susceptible	GALAP
Moderately susceptible	no weeds classified here
Moderately Tolerant	CHEAL

Tolerant	BRSNW, LAMPU, POLPE, POLCO, VERPE, VIOAR
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The following weed susceptibility is concluded after application of the **tank mix**:

3*(AG-E1-500 SC1 0,5 L/ha + Goltix Titan 565 SC 1.5 L/ha + Atpolan BIO 80 EC 1.0 L/ha):

Highly susceptible	CHEAL, GALAP, LAMPU, POLCO, STEME, VERPE
Susceptible	BRSNW
Moderately susceptible	no weeds classified here
Moderately Tolerant	no weeds classified here
Tolerant	no weeds classified here

Efficacy in the South-Eastern EPPO zone (Hungary, Slovakia)

The following weed susceptibility is concluded after **solo application** of AG-E1-500 SC1 at the dose rate of 2*1.0 L/ha:

Highly susceptible	STEME
Susceptible	AMARE, CAPBP, GALAP
Moderately susceptible	CHEAL, CHEHY, MERAN, SOLNI
Moderately Tolerant	AMBEL, POLAV, POLCO, DATST, POLPE
Tolerant	ECHCG

The following weed susceptibility is concluded after application of **tank mix**:

2*(Goltix Titan 565 SC 2.0 L/ha + AG-E1-500 SC1 1.0 L/ha):

Highly susceptible	AMARE, STEME
Susceptible	CHEAL
Moderately susceptible	POLAV, POLPE
Moderately Tolerant	AMBEL, POLCO
Tolerant	no weeds classified here

Apparently, using AG-E1-500 SC1 in the tank-mix with Goltix Titan 565 SC enhances efficacy against some weed species and broadens the spectrum of species that are controlled successfully, compared to solo application. The effect of tank-mix is of more critical importance in Poland, where the spectrum of targets effectively controlled by the solo application is rather limited compared to the South-Eastern zone, at least as exemplified here by Hungary and Slovakia. Nevertheless, the application in the tested tank-mix - in the SE EPPO zone - although not claimed in the GAP table, also deserves consideration. For details see the zRMS comments following the efficacy chapter.

RISK OF RESISTANCE

The resistance risk inherent in the active ethofumesate may be claimed low, for its mode of action likely affects more than one target enzyme involved in the fatty acid chain elongation process, but the risk inherent in target organisms is fairly variable – from low to high. Overall, the combined risk inherent in the active and in its targets should better be called medium and not low.

The most important factor allowing to reduce the resistance development risk is the fact that AG-E1-500 SC1 is to be used in 3-way or 2-way split application in a given season, that it is, at least in the North-Eastern zone, recommended to be used in tank-mix with other actives, and that its use is restricted to every 3rd year. All these “risk modifiers” taken together should reduce the selection pressure on target weeds. Hence the inherent risk modified by agronomic conditions of use may finally be considered as low.

Adverse effects on the treated crops

Phytotoxic effects

Considering the frequency and intensity of phytotoxic symptoms, as much as the respective treatments and dose rates at which these symptoms occurred, zRMS considers that the selectivity data prove acceptable crop safety, after the application of AG-E1-500 SC1 solo or in the proposed tank-mix. For details see the relevant chapter: 3.4.1.

Effect on yield and quality:

Neither following the solo nor the tank-mix application were the observed differences statistically significant, between the experimental treatments, in any of the selectivity trials and irrespective of 1N or 2N dose rate used. It is therefore concluded that no negative effect of AG-E1-500 SC1 on sugar or fodder beet **root yield amount** should be expected. No negative impact on the **root yield quality** was demonstrated either. The yield of leaves was not recorded for the fodder beet, nor was it recorded for the sugar beet, in any of the trials submitted. The “effect on yield” chapter deals exclusively with the root yield amount and quality parameters. For details see the respective chapter 3.4.3.

Selectivity extrapolation to fodder beet

All 18 field selectivity trials were carried out using sugar beet varieties, and none had used fodder beet. Since the EPPO guidance PP 275(2) *Efficacy and crop safety extrapolations for minor uses* allows for extrapolation, based on comparable competitiveness of two crops and in case of post-emergence application, zRMS considers that the non-submission of selectivity trials in fodder beet might be acceptable for Hungary, where this crop has minor status (see Table 3.2-6). In Slovakia the fodder beet is major crop, and therefore the decision on possible extrapolation is left to consideration of that cMS. In Poland, a minimum of 2 selectivity trials are required in order to extrapolate, nevertheless the use in fodder beet can be authorized otherwise, based on the art. 51, of the 1107/2009.

Effect on succeeding crops

See the zRMS comments following chapter 3.5.1 Impact on succeeding crops.

Tank cleaning

Efficacy of tank cleaning procedure has not been tested. Instead, the applicant has presented calculation concerning risk to subsequently-treated crops related to tank residue. The issue has been addressed completely and adequately. No testing of tank cleaning procedure is necessary.

GAP table – intended uses

The intended uses for AG-E1-500 SC1 are presented in the table thereafter.

Table 3.1-1 GAP table: Acceptability of intended uses

PPP (product name/code): AG-E1-500 SC1
Active substance 1: ethofumesate
Safener: not relevant
Synergist: not relevant
Applicant: ADAMA
Zone(s): Central - North-East and South-East EPPO climatic zones

Formulation type: SC
Conc. of as 1: 500 g/L
Conc. of safener: not relevant
Conc. of synergist: not relevant
Professional use: X
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures	zRMS Conclusions (efficacy)
					Method / Kind	Timing / Growth stage of crop (BBCH) & season	Max. num- ber (min. interval between applications) a) per use b) per crop/ season	kg, L prod- uct / ha a) max. rate per appl. b) max. Total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. Total rate per crop/ season	Water L/ha min / max			
1	Hungary	Sugar beet BEAVA Fodder beet BEAVC	F	Annual dicot weeds and annual-grass weeds	foliar, spraying, overall	-/ BBCH 10-18 spring	a) 2 (5) b) 2 (5)	a) 1 L/ha b) 2 L/ha	a) 500 b) 1000	100- 400	n.a.	Maximum rate of active must not exceed 1.0 kg/ha every 3 years.	A
2	Slovakia	Sugar beet BEAVA Fodder beet BEAVC	F	Annual dicot weeds and annual-grass weeds	foliar, spraying, overall	-/ BBCH 10-18 spring	a) 2 (5) b) 2 (5)	a) 1 L/ha b) 2 L/ha	a) 500 b) 1000	100- 400	n.a.	Maximum rate of active must not exceed 1.0 kg/ha every 3 years.	A
3	Poland	Sugar beet BEAVA Fodder beet BEAVC	F	Annual dicot weeds and annual-grass weeds	foliar, spraying, overall	-/ BBCH 10-18 spring	a) 3 (5) b) 3 (5)	a) 0,6 L/ha b) 1,8 L/ha	a) 300 b) 900	100- 400	n.a.	Maximum rate of active must not exceed 1.0 kg/ha every 3 years. At each timing can be applied in Tank-mix: AG-E1-50 SC1 0.5 L/ha + Goltix Titan 565 SC 1.5 L/ha + Atpolan BIO 80 EC 1.0 L/ha	A (sugar beet) N (fodder beet; possible authoriz. under art. 51)

Remarks columns:	1	Numeration necessary to allow references. Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided. Minimum interval (in days) between applications of the same product
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	PHI - minimum pre-harvest interval
			13	Remarks may include: Extent of use/economic importance/restrictions
			14	zRMSconclusions - explanation for the column 14 is below*

* Explanation for column 14 “zRMS Conclusions”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

3.2 Efficacy data (KCP 6)

Introduction

The product AG-E1-500 SC1 is an herbicide containing 500 g/L of ethofumesate (SC formulation). This application under article 33 of Regulation (EC) No. 1107/2009 submitted by the applicant is for first authorisation of the product AG-E1-500 SC1 in the Central Regulatory zone. The product was previously authorized in the Central Regulatory zone, in Austria, Belgium, Czech Republic, Germany, Netherlands, Poland and Slovakia (for PL and SK see details in Table 3.2-2).

The objective of the present dossier is to provide data on the efficacy and crop safety in support of the registration of AG-E1-500 SC1 in Poland, Hungary and Slovakia (EU Central Registration zone / North-East and South-East EPPO climatic zones) for use as an herbicide in sugar and fodder beets (post-emergence applications).

Poland is the zRMS of the submission, and Hungary and Slovakia are cMS.

To demonstrate the efficacy and crop safety of AG-E1-500 SC1 within the Central regulatory zone efficacy trials were conducted in the North-East (Poland) and the South-East (Hungary and Slovakia) EPPO climatic zones. Data from Poland (EPPO North-East climatic zone) are presented separately from data from Hungary and Slovakia (EPPO South East climatic zone). Additional supportive data from Germany and Czech Republic (Maritime EPPO climatic zone) are also presented separately. Information on the detailed composition of AG-E1-500 SC1 can be found in the confidential dossier of this submission (Registration Report - Part C).

Ethofumesate was included into Annex I of Council Directive 91/414/EEC on 01/03/2002 (Commission Directive 2002/37/EC). Council Directive 91/414/EEC was then repealed by Regulation (EC) No. 1107/2009 and on 01/11/2016, Ethofumesate was included in Annex of Commission Implementing Regulation (EU) No. 540/2011 implementing Regulation (EC) No. 1107/2009 (Commission Implementing Regulation (EU) 2016/1426). The SANCO report for ethofumesate (SANTE/10119/2016 Rev.3, finalised in July 2016) is considered to provide the relevant review information or a reference to where such information can be found.

Appendix 1 contains the list of references included in this document for supporting the evaluation.

Description of the active substance

AG-E1-500 SC1 contains one active substance: ethofumesate.

Table 0-1: Details of the active substance

Common name (ISO)	Ethofumesate
Chemical name (IUPAC)	(RS)-2-ethoxy-2,3-dihydro-3,3-dimethylbenzofuran-5-yl methanesulfonate
CAS No.	26225-79-6
Molecular formula	C ₁₃ H ₁₈ O ₅ S
Concentration	500 g/L
Chemical group	Benzofurans
Mode of action	Inhibition of very long-chain fatty acid synthesis
Biological action	Pre and post emergence herbicide
HRAC group	HRAC group 15 (former HRAC group K3)

Mode of action:

Ethofumesate is a selective and low systemic herbicide. It is absorbed mainly by coleoptile of grasses in the seedling emergence and by the roots for broad-leaved weeds. At stages of young seedlings, foliar penetration is also not negligible. This foliar penetration decreases by a factor of 6 to 10 between stages 2 and 6 leaves of the plant (*Chenopodium album* and *Amaranthus retroflexus*) (Duncan et al., 1981).

The selectivity of ethofumesate on sugar beet can be explained by penetration which is four times greater in the *Amaranthus* and *Chenopodium* than in beet where ethofumesate is less mobile and degraded more rapidly.

This active substance is recommended for the control of a large range of annual broad-leaved weeds like *Stellaria media*, *Galium aparine*, *Mercurialis annua*, *Stellaria media*, *Amaranthus retroflexus*, etc. It is also effective against grasses like *Poa annua* or *Apera spica-venti*.

Ethofumesate is used in mixture with other herbicides like metamiltron, phenmedipham, desmedipham (recently banned) and lenacil in Europe. It is used in sugar beet and fodder beet in early post-emergence to control annual weeds. In Spain, it is also used in pre-emergence in combination with metamiltron and chlorizadon.

Ethofumesate belongs to the chemical class of benzofurans herbicides (HRAC Group 15, former HRAC Group K3). It is an inhibitor of elongases, enzymes leading to long chain of fatty acids (over 18 C), precursors of waxy cuticle and suberin. It acts as an inhibitor of cell division and lipid synthesis in the seedling shoot, leading to retardation of meristem growth. The selectivity of the beet can be explained by its ability to metabolize this active substance, leading it inactive.

Ethofumesate is absorbed by young shoots and roots with translocation to the foliage. The post-emergence activity of ethofumesate is limited to young weeds as it is not absorbed by leaves after the plant has produced a mature cuticle. Sensitive weeds cease to grow after a few days and develop symptoms including discoloration, mainly bleaching and in some cases yellowing, which finally result in death of the plants. When applied in pre-emergence ethofumesate is mainly absorbed via roots of the seedlings.

Description of the plant protection product

AG-E1-500 SC1 is a soluble concentrate (SC) containing 500 g/L of ethofumesate.

The product is currently not approved anymore but was formerly authorised on beets in several countries of Central Europe (North-East and South-East EPPO zones) as follows.

Table 3.2-2: List of former authorised uses on beets of the test product (ethofumesate, 500 g/L, SC) - Central Europe, North-East and South-East EPPO climatic zones

Country	Trade name	Registration No.	Crop	Dose (L/ha)
Poland	ETHOSAT 500	R-6/0210	BBCH 11-12 and 7-10 days later	2*1 L/ha
Slovakia	ETHOSAT 500	15-11-1629	BBCH 12-19	0.2+0.4+0.5 L/ha L/ha

The following table gives an overview of the currently authorised uses on sugar beets with formulations similar to AG-E1-500 SC1 in the countries of the North-East and South-East EPPO climatic zones of the Central Regulatory zone where the product is intended to be authorised (parallel trade products are not presented).

Table 3.2-3: List of currently authorised uses on beets with formulations similar to AG-E1-500 SC1 (ethofumesate, 500 g/L, SC) in Poland, Hungary and Slovakia

Country	Trade name	Registration No.	Company	Target / use	Crop	Dose L/ha	Max nb of application
Poland	BETOSAT 500 SC	R-36/2017 h.r.	Agri-Grow Sp. z o.o.	Annual weeds	Sugar beet	0.2 L/ha	3
	ETHOFOL SC	R-145/2019	UPL Europe Ltd.	Annual weeds	Sugar and fodder beet	2*1.0 (post-em.) 1*2.0 (pre-em.)	2 ⁽¹⁾
	ETOS 500 SC	R-3/2013 h.r.	Madez- Firma Handlowo-Uslugowa Mariusz Rudnicki	Annual weeds	Sugar beet	0.2 L/ha	3
	KEMIRON KONCENTRAT 500 SC	R-68/2011	Bayer SAS	Annual weeds	Sugar beet	0.2 L/ha	3
	OBLIX 500 SC	R-107/2012	UPL Europe Ltd.	Annual weeds	Sugar and fodder beet	2*1.0 (post-em.) 1*2.0 (pre-em.)	2 ⁽¹⁾
Hungary	No products registered						
Slovakia	OBLIX	16-11-1788	UPL Europe Ltd.	Annual weeds	Sugar and fodder beet	2.0 L/ha 2*0.6 L/ha	2 ⁽¹⁾
	STEMAT SUPER	95-11-0222	Bayer, spol. sr.o	Annual weeds	Sugar and fodder beet	2*0.1-0.5 2*0.2-0.3 3*0.2-0.5	3

(1) maximum 1000 g a.s./ha every 3 years

AG-E1-500 SC1 is requested for use against annual weeds in sugar and fodder beets as follows:

Table 3.2-4: Simplified table of requested uses for AG-E1-500 SC1

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Sugar beet (BEAVA) Fodder beet (BEAVC)	Annual dicot weeds and annual grass weeds	Poland	Max. 0.6 L/ha per application max. 3 applications per season - max. 1.0 kg a.s./ha every 3 years	Min. 5 days interval
		Hungary, Slovakia	Max. 1.0 L/ha per application max. 2 applications per season - max. 1.0 kg a.s./ha every 3 years	Min. 5 days interval

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

Description of the target pests

The pests mentioned in this dossier are listed in the following table:

Table 3.2-5: Glossary of pests mentioned in the dossier

Group	EPPO code	Scientific name	Common name
Annual or biennial weeds	ABUTH	<i>Abutilon theophrasti</i>	Butter print
	AETCY	<i>Aethusa cynapium</i>	Fool's parsley
	AMARE	<i>Amaranthus retroflexus</i>	Pigweed
	AMBEL	<i>Ambrosia artemisiifolia</i>	Annual ragweed
	ANTAR	<i>Anthemis arvensis</i>	Corn chamomille
	BRUNA	<i>Brassica napus</i>	Oilseed rape
	BRSNW	<i>Brassica napus (winter)</i>	Winter Oilseed rape
	CAPBP	<i>Capsella bursa-pastoris</i>	Shepherd's purse
	CHEAL	<i>Chenopodium album</i>	Common lambsquarters
	CHEHY	<i>Chenopodium hybridum</i>	Maple-leaf goosefoot
	CIRAR	<i>Cirsium arvense</i>	Californian thistle
	DATST	<i>Datura stramonium</i>	Thorn apple
	ECHCG	<i>Echinochloa crus-galli</i>	Common barnyard grass
	FUMOF	<i>Fumaria officinalis</i>	Common fumitory
	GALAP	<i>Galium aparine</i>	Catchweed bedstraw

Group	EPPO code	Scientific name	Common name
	GERDI	<i>Geranium dissectum</i>	Cut-leaved cranesbill
	GERPU	<i>Geranium pusillum</i>	Small-flowered cranesbill
	LAMPU	<i>Lamium purpureum</i>	Purple deadnettle
	MATIN	<i>Matricaria inodora</i>	Scentless mayweed
	MERAN	<i>Mercurialis annua</i>	Annual mercury
	MYOAR	<i>Myosotis arvensis</i>	Field forget-me-not
	PANMI	<i>Panicum miliaceum</i>	Common millet
	POLAV	<i>Polygonum aviculare</i>	Knotgrass
	POLCO	<i>Fallopia convolvulus</i>	Black bindweed
	POLLA	<i>Persicaria lapathifolia</i>	Pale persicaria
	POLPE	<i>Persicaria maculosa</i>	Ladysthumb
	SETPU	<i>Setaria helvola</i>	Yellow foxtail
	SETVE	<i>Setaria verticillata</i>	Green panicgrass
	SOLNI	<i>Solanum nigrum</i>	Black nightshade
	STEME	<i>Stellaria media</i>	Common chickweed
	THLAR	<i>Thlaspi arvense</i>	Field pennycress
	VERPE	<i>Veronica persicaria</i>	Common speedwell
	VIOAR	<i>Viola arvensis</i>	Field pansy
Perennial weeds	CONAR	<i>Convolvulus arvensis</i>	Field bindweed

Weeds interact with crops to compete for resources such as light and nutrients, and in so doing have the potential to affect either the quantity or quality of the yield arising from the crop. When weed control is omitted or control is not sufficient, depending on the weed, harvest can be seriously hampered. Weed control is therefore in most cases economical and necessary.

AG-E1-500 SC1 acts to control natural populations of such weeds in the target crop, thereby reducing the weed burden of the crop and allowing the full yield potential to be reached in the absence of competition from weeds. Alongside cultural practices, such chemical control mechanisms play a critical role in weed management. The reduction in weed populations also reduces the seed return to the soil and thus makes the cultivation of following crops easier.

Ethofumesate is ineffective on all multi-annual and perennial weeds.

Table 3.2-6: 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
Sugar beet (BEAVA)	PL, HU, RO, SK	-	Annual weeds	HU, PL, RO, SK	-
Fodder beet (BEAVC)	SK	HU, PL, RO	Annual weeds	HU, PL, RO, SK	-

General information on crops tested in this dossier - Sugar beet and fodder beet

Sugar beet: Sugar beet belongs to the Altissima cultivar group of the common beet. Together with other beet cultivars, such as beetroot and chard, it belongs to the subspecies *Beta vulgaris subsp. vulgaris*.

The root of sugar beets contains high levels of sucrose. It has a conical, white, fleshy root with a flat crown. The plant consists of the root and a rosette of leaves. Sugar is formed by photosynthesis in the leaves and is then stored in the root.

Sugar beets are the second major source of the world's sugar production. Sugar beets grow exclusively in temperate zones, in contrast to sugarcane, which grows exclusively in tropical and subtropical zones. The soil must contain a large supply of plant food, be rich in humus and must retain a great deal of moisture.

Russia is the largest sugar beet producer in the world, followed by France, the US, Germany and Turkey.

The production of sugar beet in several member states of the Central zone is summarized below:

Country	Area harvested (ha)	Production (tons)	Yield (tons/ha)
Belgium	57 610	5 071 850	88.0
Czech Republic	59 210	3 661 420	61.8
Germany	408 700	29 728 300	72.7
Hungary	14 080	823 500	58.5
Poland	240 780	13 836 620	57.5
Romania	22 730	917 160	40.4
Slovakia	21 720	1 251 670	57.6
UK	108 000	7 450 000	69.0

Source: <http://www.fao.org/faostat/>, - Data from 2019

Fodder beet: *Beta vulgaris subsp. vulgaris var. crassa* is a biennial plant grown for its fleshy and swollen root. In Northern Europe, fodder beet has been used as fodder since the Middle Ages. It became a major winter feed for cattle in the 1800s. The main use of fodder beet is for feeding ruminants, though it can also be fed to pigs. The high sugar content makes fodder beet palatable and a valuable energy source. It is also a potential crop for biofuel production. Fodder beet roots that have been previously cleaned (stones and soil removed using rotating drums) can be fed whole to animals or can be chopped to facilitate intake.

Compliance with the Uniform Principles

The product AG-E1-500 SC1 complies with the Uniform Principles.

- **Guidelines:** Trials were conducted under GEP guidelines EPPO PP 1/52(3), PP 1/135(4), PP 1/152(4), PP 1/181(4) and PP 1/225(2) and followed method recommendations published by EPPO. No significant deviation to guidelines was reported.
- **Testing facility or organisation:** All trials were carried out by testing facilities officially recognised as competent to carry out efficacy testing in accordance with the requirements of Directive 93/71/EEC, and in accordance with the principles of GEP. Copies of certificates are given under point 3.7.
- **Sites:** Trials were located in areas considered to be either representative of the range of agricultural, plant health and environmental conditions (including climatic conditions) likely to be encountered in practice in the area of proposed use, or of a more severe nature of those conditions. The field were selected based on a history of infestation with annual weeds.
- **Meteorological information:** Trials included a range of climatic conditions representative of those where crops are grown commercially. Data describing the climatic conditions at application are presented in individual trial reports. In all cases, conditions were within the normal range for the areas in which the trials were conducted for the duration of the study or were considered to have represented a more severe nature of those conditions.
- **Experimental details:** In all trials, crops were managed according to local agronomical best practices. There were no significant deviations from the specified testing methods in any trial. Trials were conducted in order to investigate the effectiveness of AG-E1-500 SC1 as an herbicide against annual weeds of economical importance in sugar and fodder beets, in order to assess its efficacy under the conditions in which it will be applied.
- **Assessments**

Weed control was assessed at various intervals after application, in days after treatment (DAT), in the form of a percentage of control. All treated plots within a replicate were assessed for weed control percentage relative to the untreated plot in this replicate. This was performed individually for each weed species. For untreated plots, the ground cover percentage or the number of plants per square meter for each species was recorded.

Susceptibility of weeds to AG-E1-500 SC1 is divided as follows (after SANCO/10055/2013 Rev. 4, 3 October 2013, p. 21):

% of control	Susceptibility of the weed species
--------------	------------------------------------

≥95%	VS: very susceptible
85–94 %	S: susceptible
70–84 %	MS: moderately susceptible
50–69 %	LS: low susceptible
<50%	NS: not susceptible

Highly Susceptible (HS)	95-100 %
Susceptible (S)	85-94.9 %
Moderately Susceptible (MS)	70-84.9%
Moderately Tolerant (MT)	50-69.9%
Tolerant (T)	0-49.9 %

Crop selectivity was visually assessed at various intervals after application, in the form of a percentage relative to untreated plots. It was measured on a scale of phytotoxicity (%), 0 to 100.

Yield assessments were done, alongside with **quality measurements** such as sugar content (%), sugar yield (T/ha), sodium, potassium and amino-nitrogen contents (mmol/100g or mmol/1000g).

Information on trials submitted (3.2 Efficacy data)

The table below gives an overview of the trials used in section **3.2 Efficacy data** of this dossier.

Table 3.2-7: Presentation of the efficacy trials

Crop	Target	Country	Years	Type of trial*	Number of trials (number of valid trials)			GEP, non-GEP, official**
					Maritime zone	North-East zone	South-East zone	
Sugar beet (BEAVA)	Annual weeds	CZ	2019	E	2 (2)	-	-	GEP
			2020	E	2 (2)	-	-	GEP
		DE	2020	E	2 (2)	-	-	GEP
		HU	2019	E + MED	-	-	4 (4)	GEP
			2020	E + MED	-	-	2 (2)	GEP
		PL	2019	E + MED	-	6 (6)	-	GEP
			2020	E + MED	-	4 (4)	-	GEP
		SK	2019	E + MED	-	-	2 (2)	GEP
			2020	E + MED	-	-	5 (5)	GEP
Total Sugar beet					6 (6)	10 (10)	13 (13)	-
					29 (29)			

* E = efficacy trial, MED = minimum effective dose

** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Justification for the use of data from several climatic zones:

Trials were carried out from 2019 to 2020 under various conditions, in 5 countries and 3 climatic zones: Maritime, North-East and South-East EPPO zones.

The trials are thus fully representative of all conditions that can be encountered in all the countries where AG-E1-500 SC1 is intended to be used and are thus fully relevant to assess AG-E1-500 SC1 efficacy in countries of the Central zone belonging to the North-East and South-East EPPO climatic zones. Some results of trials conducted in the Maritime EPPO climatic zone are presented as complementary data, as they tested the requested GAPs.

In the case of herbicides in sugar and fodder beets, results from several climatic zones can be considered as relevant for the evaluation of the product in the given countries for the following reasons:

- Regarding beet crops, the agronomic conditions and cultural practices in Germany and Czech Republic are very close to what is encountered in countries belonging to the EPPO North-East and South-East zones, and thus no direct impact on the efficacy and the selectivity of the product is expected.
- Climatic conditions at application (air temperature and relative moisture) were globally homogeneous from a climatic zone to another (see Appendix 2).

A separate dossier is submitted for Maritime EPPO climatic zone (Belgium, Netherlands, Austria, ~~Czechia~~ Czech Republic and Germany).

Reference products

Reference products used in the trials are presented in the following table.

Table 3.2-8: Presentation of reference standards used in the efficacy trials in sugar beet

Reference standard	Active substance(s)	Formulation		Countries where the product is registered	Authorization number	Registered application rate (post-emergence)	Application rate per treatment in trials
		Type	Concentration of a.s.				
Zonal reference product = local standard in CZ, DE, PL and SK							
FSG 01095 H ⁽¹⁾	Metamitron + ethofumesate	SC	350 + 150 g/L	Czechia Czech Republic Germany Poland Hungary Slovakia	4674-0 025037-00/00001 R-172/2017 02.5/567/3/2009 ⁽²⁾ 15-11-1643	1.5-2.0 L/ha per app 2.0 L/ha per app 2.0 L/ha per app 1.8-4.0 L/ha per app 1.5-2.0 L/ha per app	3*2.0 L/ha 3*2.0 L/ha 3*2.0 L/ha 2*2.0 L/ha 2*2.0 L/ha
Local reference products							
BELVEDERE FORTE	Desmedipham + ethofumesate + phenmedipham	SE	100 g/L + 200 g/L+ 100 g/L	Hungary	04.2/3002-1/2012 ⁽²⁾	3*1.0 L/ha	2*1.0 L/ha
POWERTWIN 400 SC	Phenmedipham ethofumesate	SC	200 g/L+ 200 g/L	Poland	R-71/2019b	3*1.0 L/ha	3*1.0 L/ha
Standard with formulation similar to AG-E1-500 SC1							
STEMAT	Ethofumesate	SC	500 g/L	Germany	006766-60/00001	3*0.66 L/ha	3*0.66 L/ha
Local reference product also used in tank-mix with AG-E1-500 SC1							
GOLTIX TITAN	Metamitron + quinmerac	SC	525 g/L + 40 g/L	Hungary Slovakia	04.2/4287-1/2017 19-00585-AU	3*2.0 L/ha 3*2.0 L/ha	2*2.0 L/ha 2*2.0 L/ha
GOLTIX TITAN 565 SC	Metamitron + quinmerac	SC	525 g/L + 40 g/L	Poland	R-31/2015	3*2.0 L/ha	3*2.0 L/ha 3*1.5 L/ha ⁽³⁾
Adjuvants							
Atpolan Bio 80 EC	Rapeseed oil methyl ester	EC	80%	Poland	n.a.	n.a.	3*1.0 L/ha
Olejan 85 EC	Rapeseed oil	EC	85%	Poland	n.a.	n.a.	3*1.5 L/ha

⁽¹⁾ Commercial name = TORERO 500 SC in Poland; TWISTER in Slovakia, GOLTIX SUPER in Hungary, the Czech Republic and Germany

⁽²⁾ Not registered anymore

⁽³⁾ When applied in tank-mix with AG-E1-500 SC1

3.2.1 Preliminary tests (KCP 6.1)

No preliminary tests were carried out as ethofumesate has been used for many years in beets and as AG-E1-500 SC1 was formerly registered in several countries of the EU Central zone, North-East and South-East EPPO zones (including Poland and Slovakia) as follows:

Country	Trade name	Registration No.	Crop	Dose (L/ha)
Poland	ETHOSAT 500	R-6/0210	BBCH 11-12 and 7-10 days later	2*1 L/ha
Slovakia	ETHOSAT 500	15-11-1629	BBCH 12-19	0.2+0.4+0.5 L/ha L/ha

zRMS comments:

The non-submission of preliminary trials is acceptable – the proposed product is a formulation of a known active.

3.2.2 Minimum effective dose tests (KCP 6.2)

A total of 23 efficacy trials, 10 efficacy trials in the North-East EPPO zone (Poland) and 13 efficacy trials in the South-East EPPO zone (6 in Hungary and 7 in Slovakia), were carried out in 2019 and 2020 to evaluate the minimum effective dose rate of AG-E1-500 SC1 applied in post-emergence of crop against annual weeds in sugar beet.

In Poland, AG-E1-500 SC1 was applied 3 times up to a total dose of 1.8 L/ha (maximum recommended dose rate for Poland).

In Hungary and Slovakia, AG-E1-500 SC1 was applied 2 times up to a total dose of 2.0 L/ha (maximum recommended dose rate for Hungary and Slovakia).

In all countries the tested dose rates ranged from 0.5N rate to N rate.

The four herbicide programs presented are:

- **0.5N rate:** AG-E1-500 SC1 at 3*0.3 L/ha (Poland) or at 2*0.5 L/ha (Hungary and Slovakia),
- **0.8N rate:** AG-E1-500 SC1 at 3*0.48 L/ha (Poland) or at 2*0.8 L/ha (Hungary and Slovakia),
- **N rate:** AG-E1-500 SC1 at 3*0.6 L/ha (Poland) or at 2*1.0 L/ha (Hungary and Slovakia),
- **Standard:** zonal reference at 3*2.0 L/ha (Poland) or at 2*2.0 L/ha (Hungary and Slovakia).

The N rate is equal to the maximal total rate recommended per crop per season (*i.e.* 1.8 L/ha in Poland and 2.0 L/ha in Hungary and Slovakia - see GAP table). The rates applied are summarised as follows:

Poland (North-East EPPO zone)		Hungary/Slovakia (South-East EPPO zone)		Rate code
Rate per application	Total rate applied	Rate per application	Total rate applied	
0.3 L/ha	0.9 L/ha	0.5 L/ha	1 L/ha	0.5N
0.48 L/ha	1.44 L/ha	0.8 L/ha	1.6 L/ha	0.8N
0.6 L/ha	1.8 L/ha	1.0 L/ha	2 L/ha	N

Results are presented from the following trials:

Table 3.2-9: List of trials used to evaluate the minimum effective dose of AG-E1-500 SC1

EPPO zone	Country	Year	Trial ID	Testing facility	GEP or not GEP
North-East	Poland	2019	PL19HEBEAVA067A	AGRECO Sp. z o.o.	GEP
North-East	Poland	2019	PL19HEBEAVA067B	AGRECO Sp. z o.o.	GEP
North-East	Poland	2019	PL19HEBEAVA067C	AGRECO Sp. z o.o.	GEP
North-East	Poland	2019	PL19HEBEAVA067D	AGRECO Sp. z o.o.	GEP
North-East	Poland	2019	PL19HEBEAVA067G	Fertico Sp. z o.o.	GEP
North-East	Poland	2019	PL19HEBEAVA067H	Fertico Sp. z o.o.	GEP
North-East	Poland	2020	PL20HEBEAVA059A	Fertico Sp. z o.o.	GEP
North-East	Poland	2020	PL20HEBEAVA059B	Agro Research Consulting	GEP
North-East	Poland	2020	PL20HEBEAVA059C	Staphyt Sp. z.o.o.	GEP
North-East	Poland	2020	PL20HEBEAVA059H	Staphyt Sp. z.o.o.	GEP
South-East	Hungary	2019	HU19HEBEAVA100A	SynTech Research	GEP
South-East	Hungary	2019	HU19HEBEAVA100B	SynTech Research	GEP
South-East	Hungary	2019	HU19HEBEAVA100C	Növénypathyka Kft.	GEP
South-East	Hungary	2019	HU19HEBEAVA100D	Növénypathyka Kft.	GEP
South-East	Hungary	2020	HU20BEAVA101A	Növénypathyka Kft.	GEP
South-East	Hungary	2020	HU20BEAVA101B	Növénypathyka Kft.	GEP
South-East	Slovakia	2019	SK19HEBEAVA608A	Fyse, Ltd., Dep. AgroLab	GEP
South-East	Slovakia	2019	SK19HEBEAVA608B	Fyse, Ltd., Dep. AgroLab	GEP
South-East	Slovakia	2020	SK20BEAVA604A	Fyse, Ltd., Dep. AgroLab	GEP
South-East	Slovakia	2020	SK20BEAVA604B	Fyse, Ltd., Dep. AgroLab	GEP
South-East	Slovakia	2020	SK20BEAVA604C	Gemerprodukt Valice OVD	GEP
South-East	Slovakia	2020	SK20BEAVA604D	Gemerprodukt Valice OVD	GEP
South-East	Slovakia	2020	SK20BEAVA604E	UKSUP BA	GEP

Full details regarding trials implementation are given in the Point **3.2.3 Efficacy tests**.

Results focused on the last relevant efficacy assessment when the beet is near row closure = BBCH 39 (corresponding to 4 to 8 weeks after the last application).

Only relevant results are considered (at least 5 plants per m² or 5% ground cover in the untreated control plots).

Remark*: In trial SK19HEBEAVA608A the number of plants per square meter at the last assessment timing was not reported, the weed infestation in the untreated plot was only given as percentage of ground cover and the infestation levels were low (3-4%). In that case the number of p/m² at the last application was used instead, assuming that the number of weeds could not decrease afterward. In addition, the % of ground cover does not reflect the number of plants per square meter, and percentages of ground cover ranging from 3-4% often correspond to more than 5 plants per square meter.

***zRMS comments:**

The reasoning and the use of 0 DA-B weed density data has been accepted. The respective density varies between 5 and 14 plants *per* square meter, for the six weed species in question.

In the tables, results are presented first on weeds observed in at least 2 trials. Weeds observed in a single trial are then presented as complementary data.

➤ ***Results in North-East EPPO zone***

Results of a total of 10 efficacy trials carried out in Poland in 2019 and 2020 are presented in the following table [3.2-9](#) [3.2-10](#).

**Table 3.2-10: Minimum effective dose of AG-E1-500 SC1 against annual weeds in North-East EPPO zone-
Last relevant assessment - Summary**

Weed code	Nb of trials	Pest density in the untreated control (p/m ²)		% control							
				AG-E1-500 SC1 0.5N (3*0.3 L/ha)		AG-E1-500 SC1 0.8N (3*0.48 L/ha)		AG-E1-500 SC1 N (3*0.6 L/ha)		Zonal/local standard ⁽¹⁾ (3*2.0 L/ha)	
		Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
CHEAL	10	19.7	8.0-36.5	28.7	0.0-55.3	38.3	7.5-67.3	54.2	17.0-79.5	95.5	83.5-100.0
BRSNW	7	19.8	5.0-52.0	34.2	10.0-60.8	38.1	17.5-61.5	44.1	21.3-65.8	90.5	82.5-96.3
STEME	7	8.1	5.0-15.3	67.9	15.0-100.0	78.9	42.5-100	90.4	76.5-100.0	97.0	92.5-100.0
VIOAR	6	10.1	6.0-19.3	4.2	0.0-7.8	6.1	0.0-10.0	12.8	7.5-15.0	90.7	67.5-98.5
GALAP	4	8.1	5.5-12.8	77.1	63.8-92.7	80.6	66.5-97.2	86.3	71.5-100	91.6	77.8-100.0
LAMPU	3	6.8	6.0-7.3	10.0	7.5-12.5	16.3	12.5-22.5	22.1	16.3-27.5	99.0	97.0-100.0
POLCO	2	9.0	8.0-10.0	15.0	10.0-20.0	31.9	15.0-48.8	41.3	22.5-60.0	91.7	90.8-92.5
VERPE	2	10.0	6.0-14.0	11.5	10.0-13.0	12.3	12.0-12.5	16.0	15.0-17.0	97.0	94.0-100.0
AETCY	1	6.0	-	15.0	-	22.5	-	30.0	-	74.0	-
CAPBP	1	12.0	-	11.0	-	12.5	-	15.0	-	96.3	-
CIRAR	1	7.0	-	0.0	-	7.5	-	12.5	-	100.0	-
CONAR	1	24.5	-	0.0	-	8.8	-	66.3	-	85.0	-
ECHCG	1	24.8	-	0.0	-	0.0	-	0.0	-	77.0	-
FUMOF	1	13.0	-	16.8	-	21.8	-	25.3	-	75.8	-
GERPU	1	4.8	-	0.0	-	0.0	-	0.0	-	98.8	-
MATIN	1	7.5	-	62.5	-	71.3	-	73.8	-	95.8	-
POLLA	1	6.0	-	10.0	-	15.0	-	25.0	-	98.8	-
POLPE	1	15.0	-	15.3	-	21.0	-	25.0	-	98.5	-
AETCY	1	6.0	-	15.0	-	22.5	-	30.0	-	74.0	-
CAPBP	1	12.0	-	11.0	-	12.5	-	15.0	-	96.3	-
CIRAR	1	7.0	-	0.0	-	7.5	-	12.5	-	100.0	-

⁽¹⁾ FSG 01095 H = TORERO 500 SC (metamitron + ethofumesate 350 + 150 g/L SC)

zRMS comments: Table 3.2-10 summary is in agreement with data from assessments made at 30-45 DA-C, BBCH crop 38-39, depending on a trial.

Results of 10 efficacy trials conducted in 2019 and 2020 in Poland (North-East EPPO zone) showed that AG-E1-500 SC1 applied in split-up applications 3 times at 0.6 L/ha gives a satisfactory control on the key weeds *Stellaria media* (STEME) and *Galium aparine* (GALAP). Both tested lower rates gave lower results on all the weed species.

As a result, the proposed rate for AG-E1-500 SC1 in Poland is 3*0.6 L/ha (i.e. a total amount of 1.8 L/ha).

➤ **Results in South-East EPPO zone**

Results of a total of 13 efficacy trials carried out in Hungary and Slovakia in 2019 and 2020 are presented in the following table 3.2-10.

Table 3.2-11: Minimum effective dose of AG-E1-500 SC1 against annual weeds in South-East EPPO zone - Last relevant assessment - Summary

Weed code	Nb of trials	Pest density in the untreated control (p/m ²)		% control							
				AG-E1-500 SC1 0.5N (2*0.5 L/ha)		AG-E1-500 SC1 0.8N (2*0.8 L/ha)		AG-E1-500 SC1 N (2*1.0 L/ha)		Zonal standard ⁽¹⁾ (2*2.0 L/ha)	
		Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
CHEAL	10	13.6	6.0-25.0	39.8	10.0-62.5	64.1	35.0-818.8	73.2	56.0-88.8	85.1	72.5-95.5
ECHCG	6	23.2	7.3-71.0	25.0	19.0-35.0	34.6	20.0-58.8	45.5	23.8-76.3	51.3	20.5-77.5
AMARE	5	23.1	10.0-39.5	54.8	47.5-63.8	78.8	62.5-97.8	87.8	72.5-97.8	91.8	82.5-100.0
AMBEL	5	11.2	9.0-14.0	18.6	2.5-28.8	37.4	12.5-57.5	50.7	22.5-80	35.3	17.5-59.0
CHEHY	3	8.0	7.0-10.0	54.2	30.0-67.5	70.4	60.0-77.5	76.3	70.0-87.5	87.1	83.8-92.5
POLAV	3	9.3	6.5-12.0	18.3	0.0 -35.0	34.2	20.0-42.5	61.3	50.0-68.8	64.2	52.5-75.0
POLCO	3	7.4	5.0-11.8	39.2	20.0-62.5	43.8	20.0-72.5	66.3	50.0-82.5	71.8	65.3-82.5
STEME	3	5.8	5.5-6.0	74.2	65.0-92.5	92.5	87.5-100.0	98.8	97.5-100.0	99.6	98.8-100.0
CAPBP	2	12.7	7.5-17.8	48.8	30.0-67.5	64.4	45.0-83.8	94.3	88.5-100.0	95.0	90.0-100.0
DATST	2	5.5	5.0-6.0	26.3	22.5-30.0	46.3	32.5-60.0	56.3	42.5-70.0	73.8	62.5-85.0
GALAP	2	5.4	5.3-5.5	66.3	65.0-67.5	76.3	67.5-85.0	88.2	80.0-96.3	86.9	76.3-97.5
MERAN	2	11.0	10.5-11.5	48.8	35.0-62.5	64.4	63.8-65.0	72.5	70.0-75.0	74.4	70.0-78.8
POLPE	2	10.4	6.8-14.0	28.9	20.3-37.5	33.8	20.0-47.5	53.8	50.0-57.5	71.3	70.0-72.5
SOLNI	2	5.3	5.0-5.5	45.0	30.0-60.0	71.3	60.0-82.5	84.4	70.0-98.8	91.3	85.0-97.5
ABUTH	1	20.0	-	10.0	-	10.0	-	22.5	-	17.5	-
ANTAR	1	8.0	-	22.5	-	47.5	-	70.0	-	100.0	-
CONAR	1	5.8	-	0.0	-	0.0	-	0.0	-	20.0	-
PANMI	1	11.0	-	21.0	-	39.0	-	43.0	-	66.0	-
SETPU	1	10.0	-	19.0	-	24.0	-	24.0	-	38.0	-
SETVE	1	9.3	-	35.0	-	42.5	-	57.5	-	50.0	-
THLAR	1	5.0	-	52.5	-	75.0	-	78.8	-	85.0	-
VERPE	1	6.8	-	32.5	-	67.5	-	85.0	-	87.5	-

⁽¹⁾ FSG 01095 H, commercial name TWISTER in Slovakia, GOLTIX SUPER in Hungary (metamitron + ethofumesate 350 + 150 g/L SC)

zRMS comments: Table 3.2-11 summary is in agreement with data from assessments made at 34-74 DA-B, BBCH crop 38-39, depending on a trial.

Results of 13 efficacy trials carried out in Hungary and Slovakia in 2019 and 2020 (South-East EPPO zone) showed that AG-E1-500 SC1 applied in split-up applications 2 times at 1.0 L/ha gives a satisfactory control on the key weeds *Stellaria media* (STEME), *Galium aparine* (GALAP) and *Amaranthus retroflexus* (AMARE). Both lower rates tested gave lower results on all the annual weed species.

As a result, the proposed rate for AG-E1-500 SC1 in Hungary and Slovakia is 2*1.0 L/ha (i.e. a total amount of 2.0 L/ha).

zRMS comments on the Minimum Effective Dose:

The applicant's conclusions on the MED in both EPPO zones in question are valid:
The dose rate of 3*0.6 L/ha should be considered as MED for Poland,
whereas the 2*1.0 L/ha dose rate should be the MED for the South-Eastern EPPO zone.

3.2.3 Efficacy tests (KCP 6.2)

This efficacy section is separated in three parts:

- The first one presents the efficacy of AG-E1-500 SC1 applied 3 times at 0.6 L/ha (*i.e.* the maximal total target dose rate of 1.8 L/ha for Poland). This part includes results from efficacy trials carried out in the North-East EPPO zone (Poland) and in the Maritime EPPO zone (Czech Republic and Germany). In this part results from North-East and Maritime EPPO zones are first presented separately, and then merged together.
- The second one presents the efficacy of AG-E1-500 SC1 applied 2 times at 1.0 L/ha (*i.e.* the maximum total target dose rate of 2.0 L/ha) for Hungary and Slovakia. This part includes results from efficacy trials carried out in the South-East EPPO zone (Hungary and Slovakia).
- The third one presents the efficacy of AG-E1-500 SC1 applied in tank-mix with GOLTIX TITAN. This part includes results from efficacy trials in the North-East EPPO zone (Poland) and in the South-East EPPO zone (Hungary and Slovakia). In this part results from North-East and South-East EPPO zones are presented separately.

A total of 29 efficacy trials tested the efficacy of AG-E1-500 SC1 against annual weeds in sugar beet. These trials were set up in 2019 and 2020 in the North-East, Maritime and South-East EPPO zones. An overview of all available trials per country and per year is provided in the table below.

Table 3.2-12: List of trials testing the efficacy of AG-E1-500 SC1 in sugar beet

EPPO zone	Country	Year	Trial ID	Testing facility	GEP or not GEP
North-East	Poland	2019	PL19HEBEAVA067A	AGRECO Sp. z o.o.	GEP
North-East	Poland	2019	PL19HEBEAVA067B	AGRECO Sp. z o.o.	GEP
North-East	Poland	2019	PL19HEBEAVA067C	AGRECO Sp. z o.o.	GEP
North-East	Poland	2019	PL19HEBEAVA067D	AGRECO Sp. z o.o.	GEP
North-East	Poland	2019	PL19HEBEAVA067G	Fertico Sp. z o.o.	GEP
North-East	Poland	2019	PL19HEBEAVA067H	Fertico Sp. z o.o.	GEP
North-East	Poland	2020	PL20HEBEAVA059A	Fertico Sp. z o.o.	GEP
North-East	Poland	2020	PL20HEBEAVA059B	Agro Research Consulting	GEP
North-East	Poland	2020	PL20HEBEAVA059C	Staphyt	GEP
North-East	Poland	2020	PL20HEBEAVA059H	Staphyt	GEP
Maritime	Czech Republic	2019	CZ19HEBEAVA606A	Czech University of Life Sciences	GEP
Maritime	Czech Republic	2019	CZ19HEBEAVA606B	ZS Nechanice	GEP
Maritime	Czech Republic	2020	CZ20HEBEAVA602A	Czech University of Life Sciences	GEP
Maritime	Czech Republic	2020	CZ20HEBEAVA602B	ZS Nechanice	GEP
Maritime	Germany	2020	DE20HEBEAVA602A	Trial Tec	GEP
Maritime	Germany	2020	DE20HEBEAVA602B	Trial Tec	GEP
South-East	Hungary	2019	HU19HEBEAVA100A	SynTech Research	GEP
South-East	Hungary	2019	HU19HEBEAVA100B	SynTech Research	GEP
South-East	Hungary	2019	HU19HEBEAVA100C	Növénypathyka Kft.	GEP
South-East	Hungary	2019	HU19HEBEAVA100D	Növénypathyka Kft.	GEP
South-East	Hungary	2020	HU20BEAVA101A	Növénypathyka Kft.	GEP
South-East	Hungary	2020	HU20BEAVA101B	Növénypathyka Kft.	GEP
South-East	Slovakia	2019	SK19HEBEAVA608A	Fyse, Ltd., Dep. AgroLab	GEP
South-East	Slovakia	2019	SK19HEBEAVA608B	Fyse, Ltd., Dep. AgroLab	GEP
South-East	Slovakia	2020	SK20BEAVA604A	Fyse, Ltd., Dep. AgroLab	GEP
South-East	Slovakia	2020	SK20BEAVA604B	Fyse, Ltd., Dep. AgroLab	GEP
South-East	Slovakia	2020	SK20BEAVA604C	Gemerprodukt Valice OVD	GEP
South-East	Slovakia	2020	SK20BEAVA604D	Gemerprodukt Valice OVD	GEP
South-East	Slovakia	2020	SK20BEAVA604E	UKSUP BA	GEP

The following table gives an overview of the trial distribution per year, country and EPPO climatic zone.

Table 3.2-13: Summary of the number of efficacy trials testing AG-E1-500 SC1 in sugar beet

EPPO climatic zone	Country	Number of trials		Total by country	Total by climatic zone
		Year			
		2019	2020		
Maritime	Czech Republic	2	2	4	6
	Germany	-	2	2	
North-East	Poland	6	4	10	10
South-East	Hungary	4	2	6	13
	Slovakia	2	5	7	
Total		14	15	29	

The efficacy trial locations are illustrated in the map thereafter.

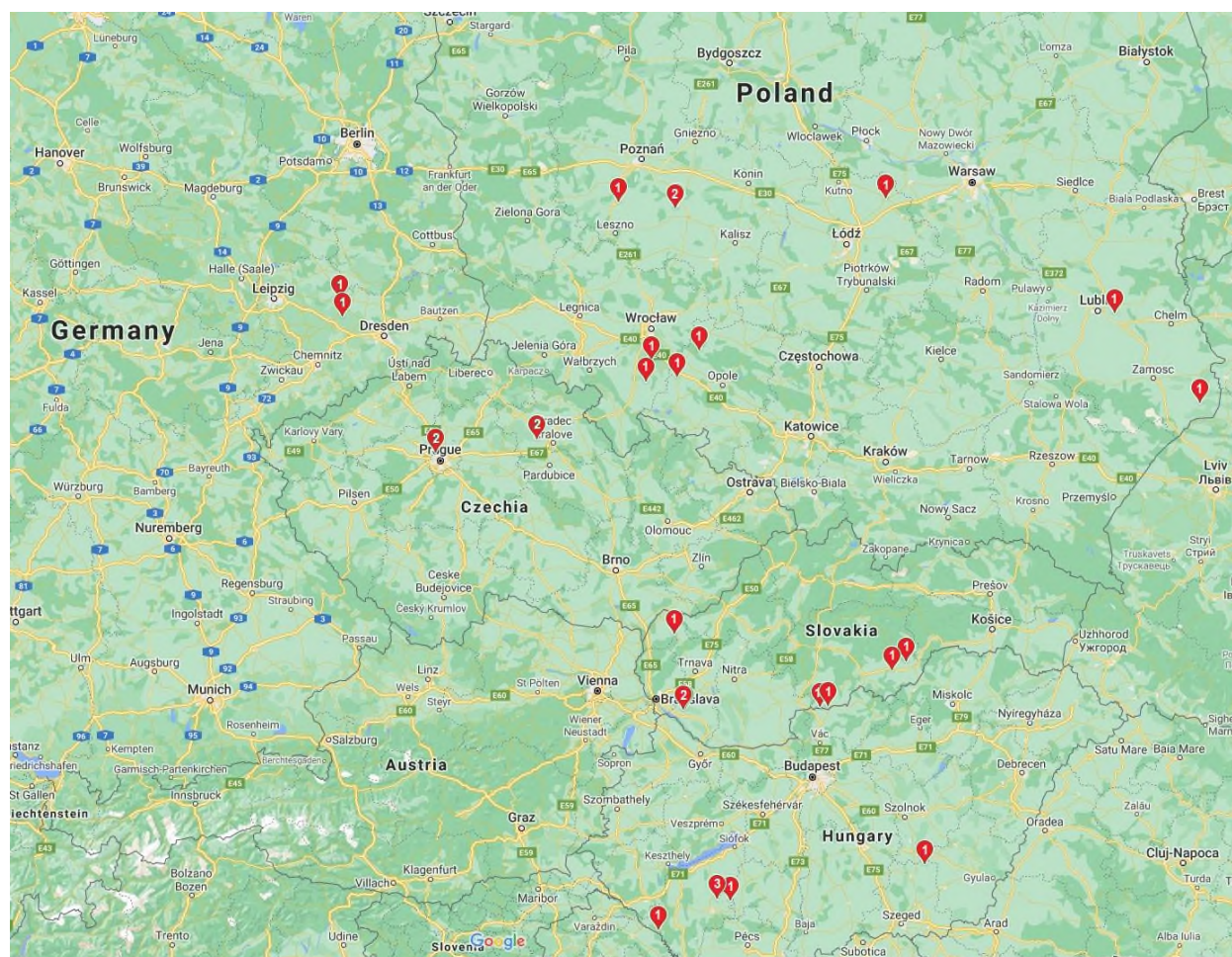


Figure 1: Locations of the 29 efficacy trials in the Czech Republic, Germany, Hungary, Poland and Slovakia

Material and methods

Details on trial methodology are summarized in the following table.

Table 3.2-14: Details on trial methodology - 29 efficacy trials

Guidelines	General guidelines	EPPO PP 1/135(4), 1/152(4), 1/181(4) (29 trials), 1/225(2) (25 trials)
	Specific guidelines	EPPO PP 1/52(3) (28 trials)
Experimental design	Plot design	Random complete block design (29 trials)
	Plot size	15-30 m ²
	Number of rep.	4 replications (29 trials)
Crop	Trials per crop	Sugar beet (29 trials)
	Varieties per crop	Antek (1), Balaton (2), BTS 6430 (1), BTS8840 (1), Danicia (1), Danzel (1), Deseda (1), Francessa (1), Gracjana (1), Gundula (1), Jagger (2), Kaplan (1), Kujavia (1), Lavenda KWS (1), Leandrus (1), Lunella (1), Nicola (1), Ondava (2), Pacific (1), Pikador (1), Silezja (1), Sixtus (1), Smart Belamia (1), Smart Renja KWS (1), Vanilla (1), Varios (1)
	Sowing period	From 24/03 23/03 to 22/04
Application	Number - Intervals	3 applications (4-6 18 trials) - interval 5-21 6-21 days (trials SK20HEBEAVA604A and SK20HEBEAVA604E included application C at 1.0 L/ha AG-E1-500 SC1). 2 applications (13 trials) - interval 6-28 6-21 days
	Crop stage (BBCH) at application	Application A: BBCH 10-12 Application B: BBCH 12-17 Application C: BBCH 14-33
	Timing of app.	Post-emergence of the crop
	Spray volumes	200-300 L/ha (29 trials)
	Application rates	3*0.3; 3*0.48; 3*0.6 L/ha in Poland, the Czech Republic and Germany 2*0.5; 2*0.8; 2*1.0 L/ha in Hungary and Slovakia
Assessment	Assessment types	- Visual % of efficacy in comparison with the untreated plot - Phytotoxicity as % of total leaf area affected by symptom where 0% = no phyto and 100% = crop destroyed - Crop vigour on a 0-10 linear scale, where 0 = no crop and 10 = the most vigorous plot, or as % in comparison with the vigorous plants.
	Statistical analysis	Data were then analysed using a two-way ANOVA on untransformed or transformed data. The probability of non-significant differences occurring between treatment means is calculated as the F probability value p(F). Student-Newman-Keuls multiple comparison test was applied to separate any significant treatment differences that may be implied by the ANOVA and these are indicated by a letter: treatment means with at least one letter in common are not significantly different according to the test initiated at the 95% confidence level.
	Assessment dates	Regularly at or just after each application and roughly at 15 DA-D, 30 DA-D, 45 DA-D and when the crop is at a growth stage BBCH 39 Last relevant assessment: depending on a trials from 30 to 70 74 days after last application
Other information	Infestation	Natural infestation (29 trials)
	Field / greenhouse	Field (29 trials)

Standard methods

The following EPPO guidelines were followed:

PP 1/135(4)	Phytotoxicity assessment
PP 1/152(4)	Design and analysis of efficacy evaluation trials
PP 1/181(4)	Conduct and reporting of efficacy evaluation trials including GEP
PP 1/225(2)	Minimum effective dose
PP 1/52(2/3)	Weeds in sugar and fodder beet

Treatments

A total of 16 efficacy trials tested the efficacy of AG-E1-500 SC1 applied 3 times at 0.6 L/ha (*i.e.* the maximal total target dose rate of 1.8 L/ha for Poland). A total of 13 efficacy trials tested the efficacy of AG-E1-500 SC1 applied 2 times at 1.0 L/ha (*i.e.* the maximal total target dose rate of 2.0 L/ha for Hungary and Slovakia). In all trials AG-E1-500 SC1 was compared to the zonal standard herbicide FSG 01095 H (metamitron 350 g/L + ethofumesate 150 g/L) applied at registered rate. In the Czech Republic, Germany, Poland and Slovakia this zonal standard is also a local standard. In Hungary, a local herbicide reference product was applied in addition to the zonal standard. Remark: In Germany, even if the zonal standard is also a local standard, another local standard with a formulation similar to AG-E1-500 SC was also tested to compare the efficacy of AG-E1-500 SC to a solo based ethofumesate product. AG-E1-500 SC1 was applied 2 or 3 times at various rates. In the efficacy part, only results of the total intended dose rate (*i.e.* a total of 1.8 L/ha of formulated product for Poland, and a total of 2.0 L/ha for Hungary and Slovakia) are presented. Results of AG-E1-500 SC1 at reduced rates are not presented in this section but in previous section **3.2.2 Minimum effective dose tests**.

Assessment methods

Weed growth stage and/or density were recorded at each application and each assessment. Weed infestation levels were assessed by counting the number of each species present in 4 x 0.25 m² quadrats in the untreated plots. Weed infestation levels in all trials were sufficient for the evaluation of the effectiveness of the test product and its comparison to the standard product. In the majority of cases, weed densities ranged from moderate to very high, with weed densities significantly exceeding the economic threshold of 5 plants per m², whereas in other cases it either equaled or approached this threshold. Overall, varied and challenging ranges of weed populations were covered by the trials.

For treated plots, a relative percentage of efficacy was estimated. Percentage control, compared to untreated plots, was made by visually estimating the % control and vigour of each weed species (untreated (no control) = 0%, complete control = 100%).

Results layout

Evaluation of efficacy focused on the last relevant assessment made approximately 4-8 weeks after last treatment, when the sugar beet is near row closure (BBCH 39). This is expected to be the main and most important evaluation timing to evaluate the weed spectrum (in accordance with EPPO guidelines). When comparing products, equivalent control is claimed when products achieve the same % of efficacy +/- 4pts. In order to define the efficacy spectrum of AG-E1-500 SC1, mean efficacy results are presented as orthogonal means for all available trials in comparison with the mean efficacy achieved by standard products.

3.2.3.1 Efficacy at 3*0.6 L/ha (total dose rate of 1.8 L/ha) (North-East EPPO zone)

A total of 10 efficacy trials carried out in 2019 and 2020 in the North-East EPPO zone (Poland) and 6 efficacy trials carried out in 2019 and 2020 in the Maritime EPPO zone (Czech Republic and Germany) tested the efficacy of AG-E1-500 SC1 at 3*0.6 L/ha (see Table 3.2-12).

Treatments

AG-E1-500 SC1 was applied 3 times at 0.6 L/ha (*i.e.* a total of 1.8 L/ha, corresponding to the maximum total recommended dose rate for Poland) and compared to the zonal/local standard herbicide FSG 01095 H applied at registered rate. Another local ethofumesate reference product (POWERTWIN 400 SC) was also applied in Poland.

In Germany, STEMAT or TRAMAT 500 was also tested in addition to the local standard, to compare the efficacy of AG-E1-500 SC to a standard product with a similar formulation.

Details of herbicide programs are given in the following table (for more details also See Table 3.2-8).

Table 3.2-15: Treatments used to evaluate the efficacy spectrum of AG-E1-500 SC1 at 3*0.6 L/ha

Test item	Products	Active substances	Application rate/appl.	Application timings ⁽¹⁾	Country
N rate (3*0.6 L/ha)	AG-E1-500 SC1	Ethofumesate 500 g/L	0.6 L/ha	ABC	All
Zonal standard = local standard in CZ, DE and PL	FSG 01095 H ⁽²⁾	Metamitron 350 g/L + ethofumesate 150 g/L	2.0 L/ha	ABC	All
Local standard (+adjuvant)	POWERTWIN 400 SC (+ Olejan 85 EC)	Phenmedipham 200 g/L + ethofumesate 200 g/L (+ rapeseed oil 85%)	1.0 L/ha (+ 1.5 L/ha)	ABC	Poland
Standard with formulation similar to AG-E1-500 SC1	STEMAT	ethofumesate 500 g/L	0.66 L/ha	ABC	Germany

⁽¹⁾ A = Early post-emergence application (BBCH 10-12), B and C with an interval of 5-10 days. In practice the theoretical interval of application was adapted to the climatic conditions

⁽²⁾ Commercial name = TORERO 500 SC in Poland; GOLTIX SUPER in Czech Republic and Germany

In the Polish trials, the local standard GOLTIX TITAN was also used for efficacy comparison with the tank-mix [AG-E1-500 SC1 + GOLTIX TITAN + adjuvant]. Results are not presented in this point but in next point **3.2.3.3 Efficacy of AG-E1-500 SC1 applied in tank-mix.**

Presentation of the results

Results are first presented separately as follows:

- 10 trials carried out in the North-East EPPO zone (Poland),
- 6 trials carried out in the Maritime EPPO zone (Czech Republic and Germany),
- a global mean is then made for all trials at the end of this section.

- North-East EPPO zone 2019-2020

Results from a total of 10 trials carried out in Poland in 2019 and 2020 are presented hereafter.

The evaluation focused on the last relevant efficacy assessment when the beet is near row closure = BBCH 39 (corresponding to 4 to 6 weeks after the last application). Only relevant results are considered (at least 5 plants per m² in the untreated control plots).

The efficacy of AG-E1-500 SC1 was compared to the zonal standard product FSG 01095 H = TORERO 500 SC (metamitron 350 g/L + ethofumesate 150 g/L) and to the local standard product POWERTWIN 400 SC (phemedipham 200 g/L + ethofumesate 200 g/L) applied with an oil-based adjuvant.

Results are presented in Table 3.2-16. In the tables, results are presented first on weeds observed in at least 2 trials. Weeds observed in a single trial are then presented as complementary data.

Table 3.2-16: Efficacy of AG-E1-500 SC1 at 3*0.6 L/ha against annual weeds - Last relevant assessment - Summary of Poland (North-East EPPO zone), 2019-2020

Summary of trials in the North-East EPPO Zone, 2019-2020											
Weed code	Nb of trials	Pest density in the untreated control (p/m ²)		% control						Number of trials where AG-E1-500 SC1 is >, = or < compared to the	
				AG-E1-500 SC1 N rate (3*0.66 L/ha) (3*0.60 L/ha)		Zonal standard ⁽¹⁾ (3*2.0 L/ha)		Local standard ⁽²⁾ (3*1.0 L/ha)			
				Mean	Min-Max	Mean	Min-Max	Mean	Min-Max		
CHEAL	10	19.7	8.0-36.5	54.2	17.0-79.5	95.5	83.5-100	-	-	10<	-
	6	19.5	8.0-30.0	64.7	17.0-75.8	-	-	99.6	98.5-100	-	6<
BRSNW	7	19.8	5.0-52.0	44.1	21.3-65.8	90.5	82.5-96.3	-	-	7<	-
	3	5.7	5.0-6.0	63.6	62.3-65.8	-	-	79.8	79.0-81.5	-	3<
STEME	7	8.1	5.0-15.3	90.4	76.5-100	97.0	92.5-100	-	-	4=, 3<	-
	3	5.4	5.0-6.0	84.8	76.5-100	-	-	99.6	99.3-100	-	1=, 2<
VIOAR	6	10.1	6.0-19.3	12.8	7.5-15.0	90.7	67.5-98.5	99.1	94.8-100	6<	6<
GALAP	4	8.1	5.5-12.8	86.3	71.5-100	91.6	77.8-100	-	-	2=, 2<	-
LAMPU	3	6.8	6.0-7.3	22.1	16.3-27.5	99.0	97.0-100	-	-	3<	-
	2	6.5	6.0-7.0	25.0	22.5-27.5	-	-	100.0	100-100	-	2<
POLCO	2	9.0	8.0-10.0	41.3	22.5-60.0	91.7	90.8-92.5	-	-	2<	-
VERPE	2	10.0	6.0-14.0	16.0	15.0-17.0	97.0	94.0-100	100.0	100-100	2<	2<
AETCY	1	6.0	-	30.0	-	74.0	-	66.0	-	1<	1<
CAPBP	1	12.0	-	15.0	-	96.3	-	98.8	-	1<	1<
CIRAR	1	7.0	-	12.5	-	100.0	-	100.0	-	1<	1<
CONAR	1	24.5	-	66.3	-	85.0	-	100.0	-	1<	1<
ECHCG	1	24.8	-	0.0	-	77.0	-	100.0	-	1<	1<
FUMOF	1	13.0	-	25.3	-	75.8	-	97.8	-	1<	1<
GERPU	1	4.8	-	0.0	-	98.8	-	100.0	-	1<	1<
MATIN	1	7.5	-	73.8	-	95.8	-	-	-	1<	-
POLLA	1	6.0	-	25.0	-	98.8	-	100.0	-	1<	1<
POLPE	1	15.0	-	25.0	-	98.5	-	99.0	-	1<	1<

⁽¹⁾ FSG 01095 H = TORERO 500 SC (metamitron + ethofumesate 350 + 150 g/L) (all trials)

⁽²⁾ POWERWIN 400 SC (phenmedipham 200 g/L + ethofumesate 200 g/L) + adjuvant OLEJAN 85 EC (rapeseed oil 85%) (6 out of 10 trials)

zRMS comments: Table 3.2-16 summary is in agreement with data from assessments made at 30-45 DA-C, BBCH crop 38-39, depending on a trial.

Results of 10 trials implemented in Poland in 2019 and 2020 showed that AG-E1-500 SC1 applied as split-up application 3 times at 0.6 L/ha gave a satisfactory level of control against the key weeds *Galium aparine* and *Stellaria media*, which are of economical importance in sugar beet in the Central zone of Europe.

- Maritime EPPO zone 2019-2020

Results from a total of 6 trials carried out in 2019 and 2020 (4 in Czech Republic and 2 in Germany) are presented hereafter.

The evaluation focused on the last relevant efficacy assessment when the beet is near row closure = BBCH 39 (corresponding to 4 to 6 weeks after the last application). Only relevant results are considered (at least 5 plants per m² in the untreated control plots).

The efficacy of AG-E1-500 SC1 was compared to the zonal and local standard FSG 01095 H = GOLTIX SUPER (metamitron 350 g/L + ethofumesate 150 g/L). In Germany AG-E1-500 SC1 was also compared to a standard product with a similar formulation (STEMAT, ethofumesate 500 g/L).

Results are presented in Table 3.2-17. In the tables, results are presented first on weeds observed in at least 2 trials. Weeds observed in a single trial are then presented as complementary data.

Table 3.2-17: Efficacy of AG-E1-500 SC1 at 3*0.6 L/ha against annual weeds - Last relevant assessment - Summary of Maritime EPPO zone (DE(2), CZ(4)), 2019-2020

Weed code	Nb of trials	Pest density in the untreated control (p/m²)		% control						Number of trials where AG-E1-500 SC1 is >, = or < compared to the zonal standard
				AG-E1-500 SC1 N rate (3*0.6 L/ha)		Zonal/local standard ⁽¹⁾ (3*2.0 L/ha)		Ethofumesate standard ⁽²⁾ (3*0.6 L/ha)		
		Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	
GALAP	6	9.8	5.0-16.0	94.3	76.3-100.0	96.8	90.0-100.0	-	-	5=, 1<
	2	6.5	5.0-8.0	99.0	99.0-99.0	-	-	99.0	99.0-99.0	-
CHEAL	4	13.3	9.0-21.0	60.0	42.5-72.5	98.4	93.8-100.0	-	-	4<
STEME	4	9.3	7.0-11.0	99.5	99.0-100.0	99.5	99.0-100.0	-	-	4=
	2	9.5	9.0-10.0	99.0	99.0-99.0	-	-	99.0	99.0-99.0	-
AMARE	2	35.5	28.0-43.0	36.3	35.0-37.5	73.2	71.3-75.0	-	-	2<
ECHCG	2	8.0	5.0-11.0	15.0	0.0-30.0	30.0	0.0-60.0	-	-	1=, 1<
POLCO	2	8.0	8.0-8.0	80.6	76.3-85.0	94.5	90.0-99.0	-	-	2<
POLPE	2	9.5	8.0-11.0	100.0	100.0-100.0	100.0	100.0-100.0	-	-	2=
THLAR	2	11.0	8.0-14.0	90.0	90.0-90.0	100.0	100.0-100.0	-	-	2<
BRNSA	1	11.0	-	50.0	-	70.0	-	-	-	1<
CAPBP	1	10.0	-	90.0	-	90.0	-	-	-	1=
DATST	1	26.0	-	80.0	-	97.3	-	-	-	1<
FUMOF	1	5.0	-	72.5	-	96.5	-	-	-	1<
GERDI	1	15.0	-	40.0	-	50.0	-	-	-	1<
MATIN	1	9.0	-	40.0	-	50.0	-	-	-	1<
MYOAR	1	7.0	-	100.0	-	100.0	-	-	-	1=
POLLA	1	6.0	-	0.0	-	70.0	-	-	-	1<

⁽¹⁾ FSG 01095 H = GOLTIX SUPER - metamitron + ethofumesate 350 + 150 g/L SC (all 6 Maritime trials)

⁽²⁾ STEMAT = ethofumesate 500 g/L (2 DE trials only)

zRMS comments: Table 3.2-17 summary is in agreement with data from assessments made at 30-45 DA-C, BBCH crop 33-44, depending on a trial.

Results of 6 trials implemented in the Czech Republic and Germany in 2019 and 2020 showed that AG-E1-500 SC1 applied as split-up application 3 times at 0.6 L/ha, controls a number of key weeds of economical importance in sugar beet in the Central zone of Europe, especially *Galium aparine*, *Stellaria media*, *Persicaria maculosa* and *Thlaspi arvense*.

As the levels of control on the key weeds were consistent between both North-East and Maritime EPPO zones, a global mean is presented hereafter for all efficacy trials testing AG-E1-500 SC1 at 3*0.6 L/ha. In addition, the EPPO Maritime zone results are comparable to results in the EPPO North-East zone because in Germany and Czech Republic the agronomic conditions and cultural practices in beet crops are very

close to what is encountered in Poland, and thus no direct impact on the efficacy of the product is expected. Furthermore, the climatic conditions at application (air temperature and relative moisture) were globally homogeneous from a climatic zone to another.

- *All trials - Maritime and North-East EPPO zones*

Results from a total of 16 efficacy trials carried out in Poland, the Czech Republic and Germany, in 2019 and 2020 are presented hereafter. The evaluation focused on the key weed species (at least 50% of efficacy in at least 2 trials), at the last relevant efficacy assessment when the beet is near row closure = BBCH 39 (corresponding to 4 to 6 weeks after the last application). Only relevant results are considered (at least 5 plants per m² in the untreated control plots).

The efficacy of AG-E1-500 SC1 (ethofumesate 500 g/L, SC) was compared to the zonal/local reference product FSG 01095 H (metamitron 350 g/L + ethofumesate 150 g/L).

Results are presented in Table 3.2-18.

Table 3.2-18: Efficacy of AG-E1-500 SC1 at 3*0.6 L/ha against key weed species - Last relevant assessment - Summary of all trials North-East and Maritime EPPO zones, 2019-2020

Summary of all trials North-East and Maritime EPO zones, 2019-2020								
Weed code	Nb of trials	Pest density in the untreated control (p/m²)		% control				Number of trials where AG-E1-500 SC1 is >, = or < compared to the zonal standard
				AG-E1-500 SC1 N rate (3*0.6 L/ha)		Zonal standard ⁽¹⁾ (3*2.0 L/ha)		
		Mean	Min-max	Mean	Min-Max	Mean	Min-Max	
CHEAL	13	18.0	8.0-36.5	54.0	17.0-75.8	96.2	83.5-100.0	13<
GALAP	10	9.1	5.0-16.0	91.1	71.5-100.0	94.7	77.8-100.0	7=, 3<
STEME	10	8.8	5.0-15.3	95.5	77.8-100.0	98.4	92.5-100.0	8=, 2<
POLCO	4	8.5	8.0-10.0	60.9	22.5-85.0	93.1	90.0-99.0	4<
POLPE	3	11.3	8.0-15.0	75.0	25.0-100.0	99.5	98.5-100.0	2=, 1<
THLAR	2	11.0	8.0-14.0	90.0	90.0-90.0	100.0	100.0-100.0	2<

⁽¹⁾ FSG 01095 H (Metamitron + ethofumesate 350 + 150 g/L SC), commercial name GOLTIX SUPER or TORERO 500 SC

zRMS comments: Table 3.2-18 summary is in agreement with data from assessments made at 30-45 DA-C, BBCH crop 33-44, depending on a trial.

Results of 16 trials implemented in Poland, the Czech Republic and Germany, in 2019 and 2020 showed that AG-E1-500 SC1 applied as split-up application 3 times at 0.6 L/ha, gave a satisfactory level of control against several weeds of economical importance in sugar beet in the Central zone of Europe, especially the key species *Galium aparine* and *Stellaria media*.

Conclusion on the efficacy of AG-E1-500 SC1 at 3*0.6 L/ha against annual weeds in sugar beet:

Data from 16 efficacy trials were used to evaluate the efficacy of AG-E1-500 SC1 applied post-emergence of the crop against annual weeds in sugar beet. AG-E1-500 SC1 was applied 3 times at 0.6 L/ha (*i.e.* a total of 1.8 L/ha corresponding to the maximum total recommended dose rate for Poland) and compared to the zonal/local standard FSG 01095 H (metamitron + ethofumesate, SC, 350 + 150 g/L) applied at registered rate. In Poland, a local herbicide reference product (POWERTWIN 400 SC) was applied in addition to the zonal standard. Remark: In Germany, even if the zonal standard is also a local standard, another standard with a formulation similar to AG-E1-500 SC was also tested to compare the efficacy of AG-E1-500 SC to a solo based ethofumesate product.

Evaluation of efficacy focused on the last relevant assessment made approximately 4 to 6 weeks after last treatment, when the sugar beet is near row close. This is expected to be the main and most important evaluation timing to evaluate the weed spectrum.

Results of 10 trials implemented in Poland in 2019 and 2020 showed that AG-E1-500 SC1 applied as split-up application 3 times at 0.6 L/ha, gave a satisfactory level of control against the key weeds *Galium aparine* and *Stellaria media*, which are of economical importance in sugar beet in the Central zone of Europe.

Results of 6 trials implemented in the Czech Republic and Germany in 2019 and 2020 showed that AG-E1-500 SC1 applied as split-up application 3 times at 0.6 L/ha controls a number of key weeds of economical importance in sugar beet in the Central zone of Europe, especially against *Galium aparine*, *Stellaria media*, *Persicaria maculosa* and *Thlaspi arvense*.

The weed spectrum of AG-E1-500 SC1 at 3*0.6 L/ha for the North-East EPPO zone is presented in the following table. Only weeds with at least 2 results are listed.

Table 3.2-19: Weed spectrum of AG-E1-500 SC1 at 3*0.6 L/ha - 4 to 6 weeks after last treatment - North-East EPPO zone, 2019-2020, 10 trials

Susceptible (85-94.9% control)	STEME (7), GALAP (4)
Low-susceptible	
Moderately Tolerant (50-69.9% control)	CHEAL (10)
Not-susceptible	
Tolerant (<50 0-49.9% control)	BRSNW (7), VIOAR (6), LAMPU (3), POLCO (2), VERPE (2)

As the levels of control on the key weed species were consistent between both North-East and Maritime EPPO zones, a global mean was made for all efficacy trials.

Based on these means, the weed spectrum of AG-E1-500 SC1 at 3*0.6 L/ha is presented in the following table. Only weeds with at least 50% of susceptibility and at least 2 results are listed.

Table 3.2-20: Weed spectrum of AG-E1-500 SC1 at 3*0.6 L/ha on key weed species - 4 to 6 weeks after last treatment - Maritime and North-East EPPO zones, 2019-2020, 16 trials

Very Highly susceptible (95-100% control)	STEME (10)
Susceptible (85-94.9% control)	GALAP (10), THLAR (2)
Moderately susceptible (70-84.9% control)	POLPE (3)
Low-Susceptible (50-69% control)	
Moderately Tolerant (50-69.9% control)	CHEAL (13), POLCO (4)

zRMS comments on efficacy in the North-Eastern zone (solo application 3*0.6 L/ha):

Comparing tables 3.2-16 and 3.2-17 reveals that the applicants' claim of the Maritime and NE data being consistent is a bit of exaggeration. Only two weeds, in the set of 10 NE zone trials, are controlled at satisfactory a level: STEME and GALAP, both showing "Susceptible" status (85-94,8% control). Both the species have shown highly susceptible in the Maritime zone trials. Although the use of supporting data from the Maritime EPPO zone seems to "enhance" susceptibility classification in the NE zone for STEME, POLCO and POLPE, it is only acceptable for STEME. Since POLCO and POLPE show completely different susceptibility levels in PL vs DE (see the table below), the averaging between these results has no valid biological meaning; these weeds remain classified as concluded from PL trials. CHEAL and GALAP stay within the same class (MT or S, respectively) even with the Maritime data used in support. THLAR, though claimed susceptible, cannot be considered for the label in Poland based on the Maritime zone data alone. Therefore the weeds other than STEME do not "benefit" from the supporting data.

	NE zone			Mar zone			NE + Mar zones		
	n	Efficacy %	susceptib. status	n	Efficacy %	susceptib. status	n	Efficacy %	susceptib. status
CHEAL	10	54,2	MT	4	60,0	MT	13	54,0	MT
	6	64,7	MT						
STEME	7	90,4	S	4	99,5	HS	10	95,5	HS
GALAP	4	86,3	S	6	94,3	S	10	91,1	S
POLCO	2	41,3	T	2	80,6	MS	4	60,9	MT
POLPE	1	25,0	T	2	100,0	HS	3	75,0	MS
THLAR				2	90,0	S	2	90,0	S

A number of other species like BRSNW, LAMPU, VERPE or VIOAR, that have been shown tolerant in the NE zone, are not considered either, for their incidence in the NE zone did not overlap with that in German or Czech trials, as can be seen when Tables 3.2-16 and 3.2-17 are compared. Finally, susceptibility for the solo application of AG-E1-500 SC1 at 3*0.6 L/ha is concluded as follows:

Highly susceptible	STEME
Susceptible	GALAP
Moderately susceptible	no weeds classified here
Moderately Tolerant	CHEAL
Tolerant	BRSNW, LAMPU, POLPE, POLCO, VERPE, VIOAR

3.2.3.2 Efficacy at 2*1.0 L/ha (total dose rate of 2.0 L/ha) (South-Eastern EPPO zone)

A total of 13 efficacy trials carried out in 2019 and 2020 in the South-East EPPO zone (Hungary and Slovakia) tested the efficacy of AG-E1-500 SC1 at 2*1.0 L/ha (see Table 3.2-11).

Treatments

AG-E1-500 SC1 was applied 2 times at 1.0 L/ha (*i.e.* a total dose rate of 2.0 L/ha), corresponding to the maximal total recommended dose rate for Hungary and Slovakia, and compared to the zonal standard herbicide FSG 01095 H applied at registered rate. In Slovakia this zonal standard is also a local standard. In Hungary, a local herbicide reference product was applied in addition to the zonal standard.

Details of herbicide programs are given in the following table (for more details also See Table 3.2-8).

Table 3.2-21: Treatments used to evaluate the efficacy spectrum of AG-E1-500 SC1 at 2*1.0 L/ha

Test item	Products	Active substances	Application rate	Application timings ⁽¹⁾	Country
N rate (2*1.0 L/ha)	AG-E1-500 SC1	Ethofumesate 500 g/L	1.0 L/ha	AB	All
Zonal standard = local standard in Slovakia	FSG 01095 H ⁽²⁾	Metamitron 350 g/L + ethofumesate 150 g/L	2.0 L/ha	AB	All
Local standard	BELVEDERE FORTE	Desmedipham 100 g/L + ethofumesate 200 g/L + phenmedipham 100 g/L	1.0 L/ha	AB	Hungary

⁽¹⁾ A = Early post-emergence application (BBCH 10-12), B and C: with an interval of 5-10 days. In practice the theoretical interval of application was adapted to the climatic conditions.

⁽²⁾ Commercial name TWISTER in Slovakia, GOLTIX SUPER in Hungary

Presentation of the results

Results from a total of 13 trials carried out in Hungary and Slovakia in 2019 and 2020 are presented hereafter.

The evaluation focused on the last relevant efficacy assessment when the beet is near row closure = BBCH 39 (corresponding to 6 to 10 weeks after the last application). Only relevant results are considered (at least 5 plants per m²). **Remark:** In trial SK19HEBEAVA608A the weed infestation in the untreated plot was only given as percentage of ground cover and the infestation levels were low. As only a few data are available the threshold of 2% ground cover is used instead of 5%. In addition, the % of ground cover does not reflect the number of plants per square meter and percentages of ground cover ranging from 2 to 5% often correspond to more than 5 plants per square meter.

The efficacy of AG-E1-500 SC1 was compared to the zonal reference product FSG 01095 H (metamitron 350 g/L + ethofumesate 150 g/L) which is also a local reference product in Slovakia, and to the local reference product BELVEDERE FORTE (desmedipham 100 g/L + ethofumesate 200 g/L + phenmedipham 100 g/L) in Hungary.

Results are presented in Table 3.2-22. In the tables, results are presented first on weeds observed in at least 2 trials. Weeds observed in a single trial are then presented as complementary data.

Table 3.2-22: Efficacy of AG-E1-500 SC1 at 2*1.0 L/ha against annual weeds - Last relevant assessment - Summary of Hungary and Slovakia (South-East EPPO zone), 2019-2020

Summary of Hungary and Slovakia (South-East E1 O Zone), 2019-2020											
Weed code	Nb of trials	Pest density in the untreated control (p/m²)		% control						Number of trials where AG-E1-500 SC1 is >, = or < compared to the	
				AG-E1-500 SC1 N rate (2*1.0 L/ha)		Zonal standard ⁽¹⁾ (2*2.0 L/ha)		Local standard ⁽²⁾ (2*1.0 L/ha)			
		Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	zonal standard	local standard
CHEAL	10	13.6	6.0-25.0	73.2	56.0-88.0	85.1	72.5-95.5	-	-	2=, 8<	-
	4	17.8	10.0-25.0	81.4	70.0-88.0	-	-	88.6	77.0-97.3	-	1>, 1=, 2<
ECHCG	6	23.3	7.3-71.0	45.5	23.8-76.3	51.3	20.5-77.5	-	-	3=, 3<	-
AMARE	5	23.1	10.0-39.5	87.8	72.5-97.8	91.8	82.5-100.0	-	-	3=, 2<	-
AMBEL	5	11.2	9.0-14.0	50.7	22.5-80.0	35.3	17.5-59.0	-	-	3>, 1=, 1<	-
	2	12.0	11.5-11.8	52.6	36.3-68.8	-	-	65.8	35.0-96.5	-	1=, 1<
CHEHY	3	8.0	7.0-10.0	76.3	70.0-87.5	87.1	83.8-92.5	-	-	1=, 2<	-
POLAV	3	9.3	6.5-12.0	61.3	50.0-68.8	64.2	52.5-75.0	-	-	1>, 1=, 1<	-
POLCO	3	7.7	5.0-11.8	66.3	50.0-82.5	71.8	65.3-82.5	-	-	2=, 1<	-
STEME	3	5.8	5.5-6.0	98.8	97.5-100.0	99.6	98.8-100.0	-	-	3=	-
CAPBP	2	12.7	7.5-17.8	94.3	88.5-100.0	95.0	90.0-100.0	-	-	2=	-
DATST	2	5.5	5.0-6.0	56.3	42.5-70.0	73.8	62.5-85.0	-	-	2<	-
GALAP	2	5.4	5.3-5.5	88.2	80.0-96.3	86.9	76.3-97.5	-	-	2=	-
MERAN	2	11.0	10.5-11.5	72.5	70.0-75.0	74.4	70.0-78.8	-	-	2=	-
POLPE	2	10.4	6.8-14.0	53.8	50.0-57.5	71.3	70.0-72.5	-	-	2<	-
SOLNI	2	5.3	5.0-5.5	84.4	70.0-98.8	91.3	85.0-97.5	-	-	1=, 1<	-
ABUTH	1	20.0	-	22.5	-	17.5	-	-	-	1=	-
ANTAR	1	8.0	-	70.0	-	100.0	-	-	-	1<	-
CONAR	1	5.8	-	0.0	-	20.0	-	-	-	1<	-
PANMI	1	11.0	-	43.0	-	66.0	-	-	-	1<	-
SETPU	1	10.0	-	24.0	-	38.0	-	-	-	1<	-
SETVE	1	9.3	-	57.5	-	50.0	-	-	-	n.r.	-
THLAR	1	5.0	-	78.8	-	85.0	-	-	-	1=	-
VERPE	1	6.8	-	85.0	-	87.5	-	-	-	1=	-

⁽¹⁾ FSG 01095 H (Metamitron 350 g/L + ethofumesate 150 g/L SC), commercial name TWISTER in Slovakia, GOLTIX SUPER in Hungary = local standard in Slovakia

⁽²⁾ Desmedipham 100 g/L + ethofumesate 200 g/L + phenmedipham 100 g/L, local standard in Hungary

zRMS comments: Table 3.2-22 summary is in agreement with data from assessments made at 31-74 DA-B, BBCH crop 37-39, depending on a trial.

Results of 13 trials implemented in Hungary and Slovakia in 2019 and 2020 showed that AG-E1-500 SC1 applied as split-up application 2 times at 1.0 L/ha, controls a number of weeds of economical importance in sugar beet in the Central zone of Europe, especially the key species *Stellaria media*, *Galium aparine*, *Amaranthus retroflexus* and *Capsella bursa-pastoris*.

Conclusion on the efficacy of AG-E1-500 SC1 at 2*1.0 L/ha against annual weeds in sugar beet:

Data from 13 efficacy trials carried out in 2019 and 2020 were used to evaluate the efficacy of AG-E1-500 SC1 applied post-emergence of the crop against annual weeds in sugar beet. AG-E1-500 SC1 was applied at a total dose rate of 2.0 L/ha, corresponding to the maximal total recommended dose rate for Hungary and Slovakia, and compared to a zonal standard product and, in some trials, to a local standard product.

Evaluation of efficacy focused on the last relevant assessment made approximately 6 to 10 weeks after last treatment, when the sugar beet is near row close. This is expected to be the main and most important evaluation timing to evaluate the weed spectrum.

Results of 13 trials implemented in Hungary and Slovakia in 2019 and 2020 showed that AG-E1-500 SC1 applied as split-up application 2 times at 1.0 L/ha, controls a number of weeds of economical importance in sugar beet in the Central zone of Europe, especially the key species *Stellaria media*, *Galium aparine*, *Amaranthus retroflexus* and *Capsella bursa-pastoris*.

The weed spectrum of AG-E1-500 SC1 at 2*1.0 L/ha for the South-East EPPO zone is presented in the following table. Only weeds with at least 2 results are listed.

Table 3.2-23: Weed spectrum of AG-E1-500 SC1 at 2*1.0 L/ha - 6 to 10 weeks after last treatment - Hungary and Slovakia, 2019-2020, 13 trials

Very susceptible (95-100% control)	STEME (3)
Susceptible (85-94% control)	AMARE (5) CAPBP (2) GALAP (2)
Moderately susceptible (70-84% control)	CHEAL (10) CHEHY (3) MERAN (2) SOLNI (2)
Low susceptible (50-69% control)	AMBEL (5) POLAV (3) POLCO (3) DATST (2) POLPE (2)
Not susceptible (<50% control)	ECHCG (7)

Highly susceptible (95-100 % control)	STEME (3)
Susceptible (85-94.9 % control)	AMARE (5), CAPBP (2), GALAP (2)
Moderately susceptible (70-84.9 % control)	CHEAL (10), CHEHY (3), MERAN (2), SOLNI (2)
Moderately Tolerant (50-69.9 % control)	AMBEL (5), POLAV (3), POLCO (3), DATST (2), POLPE (2)
Tolerant (0-49.9 % control)	ECHCG (7)

zRMS comments on efficacy in the South-Eastern zone (solo application 2*1.0 L/ha):

The applicant's conclusion and the resulting susceptibility classification shown above, are correct and valid.

3.2.3.3 Efficacy of AG-E1-500 SC1 applied in tank-mix

AG-E1-500 SC1 was applied in tank-mix with GOLTIX TITAN 565 SC / GOLTIX TITAN (metamitron 525 g/L + quinmerac 40 g/L, SC) in a total of 10 efficacy trials in the North-East EPPO zone (Poland, 2019-2020) and in a total of 7 efficacy trials in the South-East EPPO zone (2 in Hungary and 5 in Slovakia, 2020) (see Table 3.2-11).

Results are presented separately as follows:

- 10 trials carried out in the North-East EPPO zone (Poland)
- 5 trials carried out in the South-East EPPO zone (Hungary and Slovakia)

- North-East EPPO zone - 10 trials, 2019-2020

AG-E1-500 SC1 was applied 3 times at 0.5 L/ha in tank-mix with GOLTIX TITAN 565 SC at 1.5 L/ha and with an oil-based adjuvant. The efficacy of the tank-mix [GOLTIX TITAN 565 SC + AG-E1-500 SC1 + adjuvant] was compared to each product applied solo and to the zonal reference product FSG 01095 H = TORERO 500 SC (metamitron 350 g/L + ethofumesate 150 g/L).

Details of the treatments are given in the following table (for more details also see Table 3.2-8).

Table 3.2-24: Treatments used to evaluate the efficacy of AG-E1-500 SC1 applied in tank-mix - North-East EPPO zone

Test item	Products	Active substances	Application	
			rate	timings ⁽¹⁾
Tank-mix	GOLTIX TITAN 565 SC + AG-E1-500 SC1 + ATPOLAN BIO 80 EC	Metamitron 525 g/L + quinmerac 40 g/L Ethofumesate 500 g/L Rapeseed oil methyl ester 80% (adjuvant)	1.5 L/ha 0.5 L/ha 1.0 L/ha	ABC
Test product solo	AG-E1-500 SC1	Ethofumesate 500 g/L	0.6 L/ha	ABC
Zonal/local standard	FSG 01095 H = TORERO 500 SC	Metamitron 350 g/L + ethofumesate 150 g/L	2.0 L/ha	ABC
Standard solo ⁽²⁾	GOLTIX TITAN 565 SC	Metamitron 525 g/L + quinmerac 40 g/L	2.0 L/ha	ABC

⁽¹⁾ A = Early post-emergence application (BBCH 10-12), B and C: with an interval of 5-10 days. In practice the theoretical interval of application was adapted to the climatic conditions.

⁽²⁾ Only tested in 2020 trials

The evaluation focused on the last relevant efficacy assessment when the beet is near row closure = BBCH 39 (corresponding to 4 to 6 weeks after the last application). Only relevant results are considered (at least 5 plants per m² or 5% ground cover in the untreated control plots).

Results are presented in Table 3.2-25. In the tables, results are presented first on weeds observed in at least 2 trials. Weeds observed in a single trial are then presented as complementary data.

Table 3.2-25: Efficacy of AG-E1-500 SC1 in tank-mix against annual weeds - Last relevant assessment - Summary of North-East EPPO zone (Poland, 2019-2020)

Weed code	Nb of trials	Pest density in UTC (p/m ²)		% control							
				Tank mix 3*(1.5+0.5 L/ha) ⁽¹⁾		AG-E1-500 SC1 3*0.6 L/ha		Zonal/local standard 3*2.0 L/ha ⁽²⁾		GOLTIX TITAN 565 SC 3*2.0 L/ha ⁽³⁾	
		Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
CHEAL	10	19.7	8.0-36.5	98.5	96.3-100.0	54.2	17.0-79.5	95.5	83.5-100.0	-	-
	4	20.0	8.0-36.5	97.2	96.3-98.3	-	-	-	-	56.2	35.0-96.0
BRSNW	7	19.8	5.0-52.0	89.3	77.5-97.8	44.1	21.3-65.8	90.5	82.5-96.3	-	-
	4	30.4	9.8-52.0	85.3	77.5-89.9	-	-	-	-	56.9	37.5-92.5
STEME	7	8.1	5.0-15.3	98.7	91.3-100.0	90.4	76.5-100.0	97.0	92.5-100.0	-	-
	4	10.1	6.0-15.3	97.8	91.3-100.0	-	-	-	-	98.4	93.8-100.0
VIOAR	6	10.1	6.0-19.3	87.8	51.3-100.0	12.8	7.5-15.0	90.7	67.5-98.5	-	-
GALAP	4	8.1	5.5-12.8	98.4	93.8-100.0	86.3	71.5-100.0	91.6	77.8-100.0	-	-
	3	8.8	5.5-12.8	97.9	93.8-100.0	-	-	-	-	97.9	93.8-100.0
LAMPUR	3	6.8	6.0-7.3	97.9	93.8-100.0	22.1	16.3-27.5	99.0	97.0-100.0	-	-
	1	7.3	-	93.8	-	-	-	-	-	97.0	-
POLCO	2	9.0	8.0-10.0	99.0	98.0-100.0	41.3	22.5-60.0	91.7	90.8-92.5	-	-
	1	10.0	-	100.0	-	-	-	-	-	63.8	-
VERPE	2	10.0	6.0-14.0	98.9	97.8-100.0	16.0	15.0-17.0	97.0	94.0-100.0	-	-
AETCY	1	6.0	-	98.5	-	30.0	-	74.0	-	-	-
CAPBP	1	12.0	-	99.0	-	15.0	-	96.3	-	-	-
CIRAR	1	7.0	-	100.0	-	12.5	-	100.0	-	-	-
CONAR	1	24.5	-	87.0	-	66.3	-	85.0	-	-	-
ECHCG	1	24.8	-	66.0	-	0.0	-	77.0	-	-	-
FUMOF	1	13.0	-	85.0	-	25.3	-	75.8	-	-	-
GERPU	1	4.8	-	81.3	-	0.0	-	98.8	-	-	-
MATIN	1	7.5	-	87.5	-	73.8	-	95.8	-	97.0	-
POLLA	1	6.0	-	100.0	-	25.0	-	98.8	-	-	-
POLPE	1	15.0	-	96.8	-	25.0	-	98.5	-	-	-

⁽¹⁾ [GOLTIX TITAN 565 SC + AG-E1-500 SC1 + adjuvant] (metamitron 525 g/L + quinmerac 40 g/L + ethofumesate 500 g/L + rapeseed oil methyl ester) at 3*[1.5 + 0.5 + 1.0 L/ha]

⁽²⁾ FSG 01095 H =TORERO 500 SC (metamitron + ethofumesate 350 + 150 g/L) at 3*2.0 L/ha

⁽³⁾ GOLTIX TITAN 565 (metamitron 525 g/L + quinmerac 40 g/L) at 3*2.0 L/ha

Results of 10 trials implemented in Poland (North-East EPPO zone) in 2019 and 2020 showed that the tank-mix [GOLTIX TITAN 565 SC 1.5 L/ha + AG-E1-500 SC1 0.5 L/ha] applied 3 times gave an excellent and broad-spectrum level of control against most weeds of economical importance in sugar beet in the Central zone of Europe, such as *Stellaria media*, *Galium aparine*, *Chenopodium album*, *Lamium purpureum*, *Fallopia convolvulus* and *Veronica persicaria*.

zRMS comments:

Table 3.2-25 summary is in agreement with data from assessments made at 30-45 DA-C, BBCH crop 38-39, depending on a trial. Application in the tank-mix allows to extend the control spectrum over larger number of weed species compared to solo application.

- **South-East EPPO zone - 7 trials, 2020**

AG-E1-500 SC1 was applied 2 times at 1.0 L/ha in tank-mix with GOLTIX TITAN at 2.0 L/ha. The efficacy of the tank-mix [GOLTIX TITAN + AG-E1-500 SC1] was compared to each product applied solo and to the zonal reference product FSG 01095 H (metamitron 350 g/L + ethofumesate 150 g/L).

Details of the treatments are given in the following table (for more details also see Table 3.2-7 8).

Table 3.2-26: Treatments used to evaluate the efficacy of AG-E1-500 SC1 applied in tank-mix - South-East EPPO zone

Test item	Products	Active substances	Application	
			rate	timings ⁽¹⁾
Tank-mix	GOLTIX TITAN + AG-E1-500 SC1	Metamitron 525 g/L + quinmerac 40 g/L Ethofumesate 500 g/L	2.0 L/ha 1.0 L/ha	AB
Test product solo	AG-E1-500 SC1	Ethofumesate 500 g/L	1.0 L/ha	AB
Zonal standard = local standard in SK	FSG 01095 H ⁽²⁾	Metamitron 350 g/L + ethofumesate 150 g/L	2.0 L/ha	AB
Local standard solo	GOLTIX TITAN ⁽³⁾	Metamitron 525 g/L + quinmerac 40 g/L	2.0 L/ha	AB

⁽¹⁾ A = Early post-emergence application (BBCH 10-12), B and C: with an interval of 5-10 days. In practice the theoretical interval of application was adapted to the climatic conditions.

⁽²⁾ Commercial name TWISTER in Slovakia and GOLTIX SUPER in Hungary

⁽³⁾ Only tested in Hungarian trials

The evaluation focused on the last relevant efficacy assessment when the beet is near row closure = BBCH 39 (corresponding to 7 to 10 weeks after the last application). Only relevant results are considered (at least 5 plants per m²).

Results are presented in Table 3.2-27 (individual results) and Table 3.2-34 (summary). In the tables, results are presented first on weeds observed in at least 2 trials. Weeds observed in a single trial are then presented as complementary data.

Table 3.2-127: Efficacy of AG-E1-500 SC1 in tank-mix against annual weeds - Last relevant assessment - Summary of South-East EPPO zone (Hungary and Slovakia, 2020)

Weed code	Nb of trials	Pest density in UTC (p/m ²)		% control							
				Tank mix 2*(2.0+1.0 L/ha) ⁽¹⁾		AG-E1-500 SC1 2*1.0 L/ha		Zonal standard 2*2.0 L/ha ⁽²⁾		GOLTIX TITAN 2*2.0 L/ha ⁽³⁾	
		Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max
ECHCG	4	15.0	7.3-26.0	72.7	61.3-81.3	46.1	33.0-76.3	57.5	50.0-77.5	-	-
	2	21.2	16.3-26.0	67.2	61.3-73.0	-	-	-	-	48.4	38.0-58.8
CHEAL	4	11.1	6.0-16.0	85.2	80.0-91.0	62.1	56.0-70.0	78.4	72.5-81.0	-	-
	1	16.0	-	91.0	-	-	-	-	-	78.0	-
AMARE	3	22.0	20.0-23.7	95.0	87.5-98.8	84.6	72.5-92.5	88.8	82.5-92.5	-	-
AMBEL	2	9.4	9.0-9.8	67.7	44.0-91.3	63.0	46.0-80.0	57.0	55.0-59.0	75.5	59.0-92.0
POLAV	2	7.9	6.5-9.3	70.7	61.3-80.0	59.4	50.0-68.8	63.8	52.5-75.0	-	-
POLCO	2	8.6	5.3-11.8	65.7	62.5-68.8	58.2	50.0-66.3	66.4	65.3-67.5	-	-
POLPE	2	10.4	6.8-14.0	83.8	82.5-85.0	53.8	50.0-57.5	71.3	70.0-72.5	-	-
STEME	2	5.8	5.5-6.0	100.0	100.0-100.0	98.2	97.5-98.8	99.4	98.8-100.0	-	-
ANTAR	1	8.0	-	100.0	-	70.0	-	100.0	-	-	-
CAPBP	1	7.5	-	100.0	-	100.0	-	100.0	-	-	-
CHEHY	1	7.0	-	82.5	-	71.3	-	83.8	-	-	-
CONAR	1	5.8	-	20.0	-	0.0	-	20.0	-	-	-
DATST	1	6.0	-	62.5	-	42.5	-	62.5	-	-	-
GALAP	1	5.3	-	98.8	-	96.3	-	97.5	-	-	-
MERAN	1	10.5	-	78.8	-	75.0	-	78.8	-	-	-
PANMI	1	11.0	-	58.0	-	43.0	-	66.0	-	30.0	-
SETPU	1	10.0	-	43.0	-	24.0	-	38.0	-	24.0	-
SOLNI	1	5.5	-	100.0	-	98.8	-	97.5	-	-	-
THLAR	1	5.0	-	98.8	-	78.8	-	85.0	-	-	-
VERPE	1	6.8	-	100.0	-	85.0	-	87.5	-	-	-

⁽¹⁾ [GOLTIX TITAN + AG-E1-500 SC1] (metamitron 525 g/L + quinmerac 40 g/L + ethofumesate 500 g/L) at 2*[2.0 + 1.0 L/ha]

⁽²⁾ Metamitron + ethofumesate 350 + 150 g/L SC - commercial name TWISTER in Slovakia, GOLTIX SUPER in Hungary

⁽³⁾ GOLTIX TITAN (metamitron 525 g/L + quinmerac 40 g/L) at 2*2.0 L/ha

Results of 5 trials implemented in Hungary and Slovakia (South-East EPPO zone) in 2020 showed that the tank-mix [GOLTIX TITAN 2.0 L/ha + AG-E1-500 SC1 1.0 L/ha] applied 2 times gave a very good control against several weeds of economical importance in sugar beet in the Central zone of Europe, such as *Stellaria media*, *Amaranthus retroflexus* and *Chenopodium album*.

zRMS comments:

Table 3.2-27 summary is in agreement with data from assessments made at 31-74 DA-B, BBCH crop 37-39, depending on a trial.

Although the advantage of using AG-E1-500 SC1 in the tank-mix is less conspicuous compared to the NE EPPO zone, in the HU and SK trials the application in the tank-mix also allowed to slightly extend the control spectrum over larger number of weed species compared to solo application.

Conclusion on the efficacy of AG-E1-500 SC1 applied in tank-mix against annual weeds in sugar beet:

AG-E1-500 SC1 was applied in tank-mix with GOLTIX TITAN 565 SC / GOLTIX TITAN (metamitron 525 g/L + quinmerac 40 g/L, SC) in a total of 10 efficacy trials in the North-East EPPO zone (Poland, 2019-2020) and in a total of 7 efficacy trials in the South-East EPPO zone (2 in Hungary and 5 in Slovakia; 2020). The efficacy of the tank-mix was compared to each product applied solo and to the zonal standard FSG 01095 H, which is also a local standard in Poland and Slovakia.

Evaluation of efficacy focused on the last relevant assessment made approximately 4 to 10 weeks after last treatment, when the sugar beet is near “row close”. This is expected to be the main and most important evaluation timing to evaluate the weed spectrum.

Results of 10 trials implemented in Poland (North-East EPPO zone) in 2019 and 2020 showed that the tank-mix [GOLTIX TITAN 565 SC 1.5 L/ha + AG-E1-500 SC1 0.5 L/ha + adjuvant] applied 3 times gave an excellent and broad-spectrum level of control against most weeds of economical importance in sugar beet in the Central zone of Europe, such as *Stellaria media*, *Galium aparine*, *Chenopodium album*, *Lamium purpureum*, *Fallopia convolvulus* and *Veronica persicaria*.

Results of 5 trials implemented in Hungary and Slovakia (South-East EPPO zone) in 2020 showed that the tank-mix [GOLTIX TITAN 2.0 L/ha + AG-E1-500 SC1 1.0 L/ha] applied 2 times gave a very good control against several weeds of economical importance in sugar beet in the Central zone of Europe, such as *Stellaria media*, *Amaranthus retroflexus* and *Chenopodium album*.

zRMS comments:

The following weed susceptibility is concluded for the **North-Eastern EPPO zone (Poland)** after the application of the test item in **3-way tank-mix** Goltix Titan 565 SC + AG-E1-500 SC1 + Atpolan BIO 80 EC:

Highly susceptible	CHEAL, GALAP, LAMPU, POLCO, STEME, VERPE, VIOAR
Susceptible	BRSNW
Moderately susceptible	no weeds classified here
Moderately Tolerant	no weeds classified here
Tolerant	no weeds classified here

The following weed susceptibility is concluded for the **South-Eastern EPPO zone (Hungary, Slovakia)** after the application of the test item in **2-way tank-mix** Goltix Titan 565 SC + AG-E1-500 SC1:

Highly susceptible	AMARE, STEME
Susceptible	CHEAL
Moderately susceptible	POLAV, POLPE
Moderately Tolerant	AMBEL, POLCO
Tolerant	no weeds classified here

Please note that some weeds like CAPBP, CHECHY, MERAN, SOLNI, POLAV or DATST, did not appear, or had appeared only in single trials of all those testing the tank-mix in the South-Eastern zone, while they were assessed in solo application treatments. Their susceptibility is originally shown following the results of solo application, in the Table 3.2-23. It should also be considered, in order to conclude finally about the overall efficacy of the tank-mix application, as it can be expected that weed species vulnerable to solo product would respond to the proposed tank-mix either. Such hypothetical classification for tank-mix application in the South-Eastern zone is concluded below:

Highly susceptible	AMARE , STEME
Susceptible	CHEAL, CAPBP, GALAP
Moderately susceptible	POLAV, POLPE, CHEHY (3), MERAN (2), SOLNI (2)
Moderately Tolerant	AMBEL, POLCO, DATST
Tolerant	ECHCG

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

This section was written in accordance with the EPPO Standard PP1/213(4) recommendations.

Introduction

The product AG-E1-500 SC1 is an herbicide containing 500 g/L of ethofumesate (SC formulation) intended for professional use as herbicide for the control of grassweeds and broadleaved weed species in sugar beets.

“Resistance” is defined as the naturally occurring, inheritable adjustment in the ability of individuals in a population to survive a treatment that would normally give effective control. Although resistance can often be demonstrated in the laboratory this does not necessarily mean that pest control in the field is reduced. “Practical resistance” is the term used for loss of field control due to a shift in sensitivity (OEPP/EPPO, 1988). The risk of resistance arising is dependent on the mode of action of the active substance and the inherent ability of the target plant to develop resistance.

Mode of action of the active substance

Ethofumesate belongs to the chemical group of benzofurans. The general mode of action is the inhibition of the fatty acid and lipid biosynthesis. Until June 2020, the mode of action of ethofumesate was classified according to HRAC (Herbicide Resistance Action Committee) in group N and according to the WSSA (Weed Science Society of America) in group 16. From June 2020¹, the HRAC updated the mode of action classification system. From all those updates, they reclassified the benzofurans (Former HRAC Group N/16), previously classified as “Lipid Synthesis Inhibition – not ACCase”, to “Inhibition of Very Long-Chain Fatty Acid Synthesis” since reports concluded this is the mode of action of benzofurans (Abulnaja *et al.* Phytochemistry 1992 31(4) 1155-1159; Baldwin *et al.* J Experimental Botany 2003 54 (385) 1289-1294; Barrett *et al.* Biochemical Soc Transactions 1994 22(3) 260S; Lechelt-Kunze *et al.* Pest Management Sci 2003 59(8) 847-856; Magnucka *et al.* Pest Management Sci. 2009 65(10) 1065-1070).

Therefore, as shown in the following table, ethofumesate belongs to the benzofurans chemical family, and belongs to HRAC group 15 - Inhibition of Very Long-Chain Fatty Acid Synthesis (former group HRAC N).

Table 0-1: Mode of action of ethofumesate and chemical family

Mode of action according to HRAC	HRAC GROUP 15 Inhibition of Very Long-Chain Fatty Acid Synthesis
Former group HRAC	N (Inhibition of lipid synthesis - not ACCase inhibition)
Chemical family	Benzofurans

The following table shows the new classification with active substances belonging to the new group HRAC/WSSA Group 15.

¹ Global HRAC MOA Classification working group report – Version: June, 2, 2020

Table 0-2: HRAC GROUP 15 - Inhibition of Very Long-Chain Fatty Acid Synthesis

Active substances	Previous classification	New classification
cafenstrole, fentrazamide, ipfencarbazone	Other and tetrazolinone	Azolyl-carboxamides
anilofos, Piperophos	Other	α -Thioacetamides
pyroxasulfone, fenoxasulfone	Others	Isoxazoles
indanofan, tridiphan	Unknown, other	Oxiranes
acetochlor, alachlor, butachlor, butenachlor, diethyl-ethyl, di-methachlor, dimethenamid, metazachlor, metolachlor, pethoxamid, pretilachlor, propachlor, propisochlor, thenylchlor, allidochlor=CDAA, delachlor, prynachlor	Chloroacetamides	α -Chloroacetamides
mefenacet, flufenacet	Oxyacetamides	α -Oxyacetamides
butylate, cycloate, dimepiperate, EPTC, esprocarb, molinate, orbencarb, pebulate, prosulfocarb, thiobencarb=benthocarb, tiocarbazil, tri-allate, vernolate	Thiocarbamates	No change
benfuresate, ethofumesate	Benzofurans	No change

Mode of action of Ethofumesate: Ethofumesate is a selective systemic herbicide. It is an inhibitor of elongases, enzymes leading to long chain of fatty acids (over 18 C), precursors of waxy cuticle and ~~sober-~~ing **suberin**. It acts as an inhibitor of cell division and lipid synthesis in the seedling shoot, leading to retardation of meristem growth. The selectivity of the beet can be explained by its ability to metabolize this active substance, rendering it inactive.

Mechanism of resistance

Whilst the exact target site of HRAC Group 15 herbicides is unknown, it involves inhibition of enzymes involved in the biosynthesis of very long chain fatty acids (VLCFAs) and prevention of cell division. Cases of resistance to HRAC group 15 herbicides are very rare.

Evidence of resistance

HRAC group 15:

HRAC group 15 is the mode of action group for actives substances belonging to the families of azolyl-carboxamides, benzofurans, α -chloroacetamides, isoxazoles, oxiranes, α -thioacetamides and thiocarbamates. Ethofumesate belongs to the family of benzofurans.

Worldwide, resistance to HRAC group 15 is known in weeds such as *Alopecurus myosuroides*, *Avena fatua* and in some *Echinochloa* species and *Lolium* species. In these weeds, multiple-resistance has also been reported to other groups of herbicides.

Resistance of *Alopecurus myosuroides* against HRAC 15 herbicides was first reported from Germany in 2007: multiple resistance has evolved to flufenacet from the HRAC 15 (α -oxyacetamides family) and other herbicides from former HRAC A/1, B/2 and C/7 groups

Resistance of *Avena fatua* against HRAC 15 herbicides was first reported from Canada in 1989. During the 1990s resistance of wild-oat was also reported from USA and from other sites in Canada.

Resistance of *Echinochloa* species to HRAC group 15 was first reported in China (1993) and later in Philippines (2005).

Resistance of *Lolium perenne ssp. multiflorum* against HRAC group 15 herbicides was first reported in Idaho in 2005. It was also reported in 2018 in France, the UK and the USA (Oregon and Washington). For every cases, the resistance was related to flufenacet from the family of α -oxyacetamides.

Resistance against other monocotyledons such as *Lolium rigidum* and *Poa annua* was reported from Australia and USA.

The table thereafter shows the resistant weeds species to HRAC group 15 in Europe - actives substances belonging to the HRAC group 15 are highlighted in yellow.

Table 0-3: Weed species resistant to HRAC group 15 – Situation in Europe in October 2020

Former HRAC group	Species	Country	First Year
K3	<i>Alopecurus myosuroides</i>	<u>2007 - Germany *Multiple - 4 SOAs</u> Crop: Wheat. Multiple resistance has evolved to herbicides in the former Groups A/1, B/2, C2/7, and K3/15: resistance to chlorotoluron, fenoxaprop-P-ethyl, flufenacet , isoproturon, mesosulfuron-methyl, and pinoxaden	2007
N	<i>Alopecurus myosuroides</i>	<u>2011 - Sweden *Multiple - 3 SOAs</u> Crop: Wheat. Multiple resistance has evolved to herbicides in the former Groups A/1, B/2, and N/8: resistance to fenoxaprop-P-ethyl, flupyr-sulfuron-methyl-sodium, prosulfocarb , and pyroxsulam	
K3	<i>Lolium perenne ssp. multiflorum</i>	<u>2018 - France</u> Crop: Wheat. Resistance to flufenacet - Group K3/15. <u>2018 - United Kingdom</u> Crop: Wheat. Resistance to flufenacet - Group K3/15.	2005

Source: www.weedscience.org consulted on October 2020*

(MoA presented in this table refers to former HRAC code) / SOA = site of action

In yellow: **bolded**: actives substances belonging to the HRAC group 15 (HRAC 2021)

zRMS comments:

*With respect to Europe the information given in the above Table 0-3 remains current in January 2022.

Only 4 cases were reported in Europe against HRAC group 15 herbicides. Three cases out of 4 were related to flufenacet which belongs to the family of α -oxyacetamides. The other one was related to prosulfocarb (thiocarbamates family) in Sweden.

Over 20 populations of ethofumesate-resistant *Poa annua* were found in grass seed fields in Oregon. These *Poa annua* populations evolved multiple resistance to the extent that they were also resistant to triazines and urea herbicides. So far, no resistance of dicotyledonous weeds to ethofumesate was reported, neither in other grass species.

Table 0-4: Weed species resistant to ethofumesate – Worldwide situation in January 2021

Weed species	Number of cases (date of reporting) Country	Cross-resistance	Multiple resistance (HRAC group involved)	actives involved
<i>Poa annua</i>	1 (1994) United States (Oregon)	0	0	ethofumesate

HRAC website, accessed on 6th Jan. 2021*

zRMS comments:

* The same data available in January 2022.

Cross resistance

With the only resistant population of *Poa annua*, no cross resistance was observed.

Sensitivity data

No sensitivity data baseline is available because it is an old compound used since the seventies.

Resistance risk analysis

Determination of inherent risk of resistance for target weeds

Table 3.3-5 displays target weed species of AG-E1-500 SC1 (annual dicot weeds) according to their inherent risk to develop resistance to herbicides across HRAC groups and countries. This classification is based on the frequency of the recorded resistance occurrence to all herbicides. Those data are from <http://www.weedscience.com/>

The inherent risk is classified according to the number of resistant biotypes already recorded in the weeds science data base:

HIGH: number >5 / MEDIUM: number between 1 and 4 / LOW: no case

Table 0-5: Inherent risk of weeds to develop resistance to herbicides

EPPO code	Weed species	Number of herbicide resistant biotypes across all HRAC groups			inherent risk to develop resistance to herbicides
		Geographical Europe	Outside Europe	Worldwide	
ALOMY	<i>Alopecurus myosuroides</i>	32	3	35	high
ECHCG	<i>Echinochloa crus-galli</i>	15	31	46 (48 in Jan. 2022)	
POAAN	<i>Poa annua</i>	11	37	48	
AMARE	<i>Amaranthus retroflexus</i>	13	34	47 (48 in Jan. 2022)	
CAPBP	<i>Capsella bursa-pastoris</i>	3	5	8	
CHEAL	<i>Chenopodium album</i>	17	32	49	
GALAP	<i>Galium aparine</i>	0	6	6	
PAPRH	<i>Papaver rhoeas</i>	15	0	15	
SENVU	<i>Senecio vulgaris</i>	10	6	16	
SINAR	<i>Sinapis arvensis</i>	2	11	13	
SOLNI	<i>Solanum nigrum</i>	10	4	14	medium
STEME	<i>Stellaria media</i>	12	11	23	
ANTAR	<i>Anthemis spp.</i>	0	1	1	
DATST	<i>Datura stramonium</i>	0	1	1	
POLCO	<i>Fallopia convolvulus</i>	2	2	4	
MATIN	<i>Matricaria recutita</i>	5	0	5	
POLAV	<i>Polygonum aviculare</i>	2	0	2	
POLPE	<i>Polygonum persicaria</i>	3	2	5	low
POROL	<i>Portulaca oleracea</i>	0	1	1	
THLAR	<i>Thlaspi arvense</i>	0	3	3	
ANGAR	<i>Anagallis arvensis</i>	0	0	0	
CHEHY	<i>Chenopodium hybridum</i>	0	0	0	
CHEVU	<i>Chenopodium vulvaria</i>	0	0	0	
FUMOF	<i>Fumaria officinalis</i>	0	0	0	
LAMSS	<i>Lamium spp.</i>	0	0	0	
MERAN	<i>Mercurialis annua</i>	0	0	0	
VERSS	<i>Veronica spp.</i>	0	0	0	
VIOAR	<i>Viola arvensis</i>	0	0	0	

Source: **International herbicide-resistant weed database**, <http://www.weedscience.org/Pages/SpeciesbySOATable.aspx>; accessed on 14th Dec. 2020*

zRMS comments:

* Table 0-5 provides estimation of weeds` propensity to develop resistance to **any** herbicide. Of all the weeds shown, only ALOMY and POAAN demonstrate resistance to ethofumesate, according to data shown in the two preceding tables. Until January 2022 the situation has not changed considerably, compared to December 2020.

Results reported in the previous table show a major risk in Europe for grasses as *Poa annua*, the most common in beet crops and for spring broad-leaved weeds corresponding to the crops involved with AG-E1-500 SC1 as *Chenopodium album*, *Amaranthus retroflexus* or *Solanum nigrum*. These weeds present in maize and whose resistance comes mainly from a pressure of atrazine, exhibit many characteristics that favour the accumulation of herbicide resistance mechanisms. These characteristics include large populations of widespread distribution in cropping areas (it can be find in aestival and spring crops), high reproductive capacity and genetic flexibility.

Determination of inherent risk of resistance for the active substance

Considering the fact that only 1 resistance case to ethofumesate was recorded worldwide (in the United States, Oregon, 1994) despite the fact that this active substance is widely used since a number of decades, it can be concluded that the inherent risk of resistance to ethofumesate is very low.

Determination of inherent agronomic risk for resistance development

The risk results from pressure applied to a population of weeds over several years. The occurrence of resistance may result from the application of one herbicide or several herbicides with a similar mode of action, often associated with monocropping and reduced cultivation practices. These cultivation practices have an effect on weed seedbank.

From the previous chapters we can note that only 1 biotype is recorded as resistant to ethofumesate.

However, the key strategy to manage the resistance development is the reduction of pressure on populations by using combined techniques (HRAC guideline):

Cultivation

Cultivation does not exert a chemical selection pressure and limit the soil seed bank. One of the most efficient for annual weeds is ploughing or deep tillage prior to control of emerged plants. Ploughing and deep tillage also bury new seeds (15-20 cm for ploughing).

Crop rotation

Crop rotation avoids successive crops in the same field which require herbicides with the same mode of action for control of the same weed species.

Different crops will allow rotation of herbicides having a different site of action and can interrupt the growth season of the weed.

A strongly competitive crop in the rotation can give a better chance to restrict weed seed production.

Including autumn and spring sown crops within a rotation increases the range of weed species and reduces overall numbers. This makes easier the weeding.

Generally, sugar beets are cultivated exclusively in crop rotations with an interval of at least 3 years and it is common practice to apply sugar beet herbicides either as tank mixtures or as sequential applications using different herbicides.

Number of application / mixture used in tank mixes

In practice, the registered rate of AG-E1-500 SC1 is split into 2 or 3 applications. AG-E1-500 SC1 is mixed with other herbicides from different families (for example metamitron and phenmedipham) to broaden the spectrum and control the risk of resistance. This minimises ~~at the maximum~~ the selection pressure on ethofumesate, added to the crop rotations with an interval of generally at least 3 years.

Alternating herbicides

In addition to mixtures, alternating herbicides with different modes of action used in the frame of herbicide programs is an excellent tool to limit the resistance development. This is supported by the same justifications as for the mixture.

Conclusions for inherent agronomic risk

It can be concluded that the inherent agronomic risk is low.

Determination of the combined risk of resistance with AG-E1-500 SC1

- Inherent risk of resistance for target weeds: low to high
- Inherent risk of resistance for the active substance: very low
- Inherent agronomic risk for resistance development: low

In conclusion, even if the inherent risk for the target weeds can be high, considering the fact that the inherent risk of resistance for the active substance is very low and that the inherent agronomic risk for resistance development is low, **it can be concluded that the risk of resistance with AG-E1-500 SC1 used according to the GAP is low.**

zRMS comments on the resistance risk:

The resistance risk inherent in the active ethofumesate may be claimed low, for its mode of action likely affects more than one target enzyme involved in the fatty acid chain elongation process (Cobb and Reade 2010). Low incidence of resistance cases, in spite of the broad use of this active, seems to confirm such possibility. On the other hand, the risk inherent in target organisms is fairly variable - low to high - as demonstrated by the incidence of resistance to other herbicides in some weeds indicated by the applicant as being of key importance in beet crops. Overall then, the combined risk inherent in the active and in its targets should better be called medium, instead of low.

From the practical point of view the most important factor allowing to reduce the risk is the fact that AG-E1-500 SC1 is to be used in 3-way or 2-way split application in a given season, that at least in the North-Eastern zone it is recommended to be used in tank-mix with other actives (metamitron and quinmerac, groups 5 and 4 HRAC, respectively) and that its use is restricted to every 3rd year, essentially in line with the standard frequency with which sugar beet can be grown within a typical crop rotation. All these “risk modifiers” taken together, plus standard tillage practice, should reduce the selection pressure on target weeds. Therefore, and provided they are included in product label and implemented by the end user, the inherent risk modified by agronomic conditions of use may finally be considered as low.

Andrew H. Cobb and John P.H. Reade, 2010. *Herbicides and Plant Physiology*, Second Edition: 168.

3.4 Adverse effects on treated crops (KCP 6.4)

A total of 18 specific selectivity trials in weed free conditions were carried out in sugar beet. Trials were conducted in 2019 and 2020, 6 in the North-East EPPO zone (Poland), 8 in the South-East zone (4 trials in Hungary and 4 trials in Slovakia) and 4 in the Maritime EPPO zone (Germany) in order to assess the adverse effects of AG-E1-500 SC1 on sugar beets.

For the North-East EPPO zone, in addition to the results from trials carried out in Poland, the German and Czech results are used as complementary data.

For the South-East EPPO zone, in addition to the results from trials carried out in Hungary and Slovakia, the Polish results and the German results are used as complementary data.

In addition, AG-E1-500 SC1 was registered in Slovakia from 1998 to 2018 (Registration No. 15-11-1629) and no phytotoxicity was reported during this whole period of 20 years. Moreover, in Poland and Germany the requested rate for South-East zone (2*1.0 L/ha) has been registered in the past and no phytotoxicity was reported.

Table 3.4-1: Presentation of the selectivity trials

Crop	Country	Years	Type of trial*	Number of trials (number of valid trials)			GEP, non- GEP, official**
				North-East zone	South-East zone	Maritime zone	
Sugar beet (BEAVA)	PL	2019	S+Y+Q	6 (6)	-	-	GEP
	HU	2019	S+Y+Q	-	4 (4)	-	GEP
	SK	2019	S+Y+Q	-	4 (4)	-	GEP
	DE	2019	S+Y+Q	-	-	1 (1)	GEP
		2020	S+Y+Q	-	-	3 (3)	GEP
TOTAL				6 (6)	8 (8)	4 (4)	-
				18 (18)			

* S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment

** Official: carried out by a national official organisation

AG-E1-500 SC1 was applied up to twice the maximum requested dose rate in all trials. The effects of AG-E1-500 SC1 were compared to a standard product applied at N and 2N rates. In addition, the phytotoxicity on crop was assessed in the 29 efficacy trials presented in point 3.2.3 of this dossier. Selectivity results of these efficacy trials are presented in this section 3.4.

Reference products used in the trials are presented in the following table.

Table 3.4-2: Presentation of reference standards used in the selectivity trials in sugar beet

Reference standard	Active substance(s)	Formulation		Countries where the product is registered	Authorization number	Registered application rate (post-emergence)	Application rate per treatment in trials
		Type	Concentration of a.s.				
Zonal reference product							
FSG 01095 H ⁽¹⁾	Metamitron + ethofumesate	SC	350 g/L + 150 g/L	Poland Slovakia Germany	R-172/2017 15-11-1643 025037-00/00001	2.0 L/ha per application 1.5-2.0 L/ha per application 2.0 L/ha per application	3*2.0 & 3*4.0 L/ha 2*2.0 & 2*4.0 L/ha 3*2.0 & 3*4.0 L/ha
Local reference products							
BELVEDERE FORTE	Desmedipham + ethofumesate + phenmedipham	SE	100 g/L + 200 g/L+ 100 g/L	Hungary	04.2/3002-1/ 2012 ⁽²⁾	3*1.0 L/ha	2*1.0 & 2*2.0 L/ha
Local reference product also used in tank-mix with AG-E1-500 SC1							
GOLTIX TITAN 565 SC	Metamitron + quinmerac	SC	525 g/L + 40 g/L	Poland Germany	R-31/2015 007529-00	3*2.0 L/ha 3*2.0 L/ha	3*1.5 & 3*3.0 L/ha 3*1.5 & 3*3.0 L/ha
Adjuvant used in the tank-mix							
Atpolan Bio 80 EC	Rapeseed oil methyl ester	EC	80%	Poland Germany	n.a. n.a.	n.a. n.a.	3*1.0 & 3*2.0 L/ha 3*1.0 & 3*2.0 L/ha

⁽¹⁾ Commercial name = TORERO 500 SC in Poland; TWISTER in Slovakia, GOLTIX SUPER in Hungary and Germany

⁽²⁾ Not registered anymore

An overview of all available selectivity trials per country and per year is given in the table below.

Table 3.4-3: List of the selectivity trials

EPPO zone	Country	Year	Trial ID	Testing facility	GEP or not GEP
North-East	Poland	2019	PL19HSBEAVA066A	Fertico Sp. z o.o.	GEP
North-East	Poland	2019	PL19HSBEAVA066B	Fertico Sp. z o.o.	GEP
North-East	Poland	2019	PL19HSBEAVA066C	Staphyt Sp. z o.o.	GEP
North-East	Poland	2019	PL19HSBEAVA066D	Staphyt Sp. z o.o.	GEP
North-East	Poland	2019	PL19HSBEAVA066E	Poznań University of Life Sciences	GEP
North-East	Poland	2019	PL19HSBEAVA066F	Poznań University of Life Sciences	GEP
South-East	Hungary	2019	HU19HSBEAVA100A	SynTech Research	GEP
South-East	Hungary	2019	HU19HSBEAVA100B	SynTech Research	GEP
South-East	Hungary	2019	HU19HSBEAVA100C	Növénypatyika Kft.	GEP
South-East	Hungary	2019	HU19HSBEAVA100D	Növénypatyika Kft.	GEP
South-East	Slovakia	2019	SK19HSBEAVA604A	GEMERPRODUKT VALICE OVD	GEP
South-East	Slovakia	2019	SK19HSBEAVA604B	GEMERPRODUKT VALICE OVD	GEP
South-East	Slovakia	2019	SK19HSBEAVA604C	Fyse, Ltd., Dep. AgroLab	GEP
South-East	Slovakia	2019	SK19HSBEAVA604D	Fyse, Ltd., Dep. AgroLab	GEP
Maritime	Germany	2019	DE19HSBEAVA602A	Hetterich Fieldwork	GEP
Maritime	Germany	2020	DE20HSBEAVA600A	Biochem Agrar GmbH	GEP
Maritime	Germany	2020	DE20HSBEAVA605A	Biochem Agrar GmbH	GEP
Maritime	Germany	2020	DE20HSBEAVA605B	Biochem Agrar GmbH	GEP

The locations of the selectivity trials are illustrated on the map below.

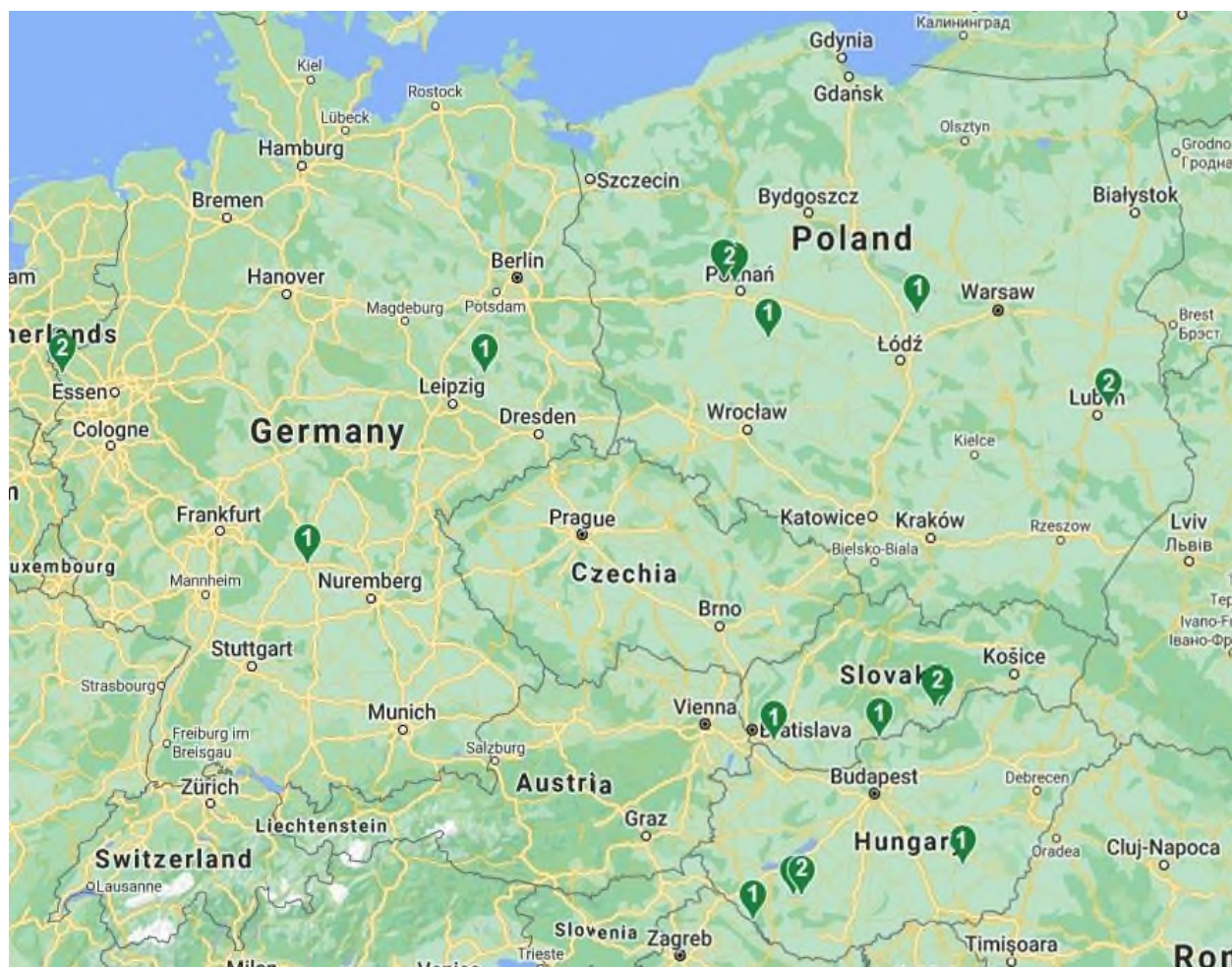


Figure 2: Locations of the 18 selectivity trials in Poland, Hungary, Slovakia and Germany.

Material and methods

Table 3.4-4: Details on trial methodology - 18 selectivity trials

Guidelines	General guidelines	EPPO PP 1/135(4), 1/152(4), 1/181(4), 1/225(2) (18 trials)
	Specific guidelines	EPPO PP 1/52(3) (16 trials)
Experimental design	Plot design	Randomised complete blocks (18 trials)
	Plot size	21-30 m ²
	Number of rep.	4 replications (18 trials)
Crop	Trials per crop	Sugar beet (18 trials)
	Varieties per crop	Antek (1), BTS 6000 (1), Fiorella (1), Gundula (1), Jagiellon (1), Jagoda (1), Kujavia (1), Maribo (1), Mazur (1), Ozon, (1), Panorama (1), Python (1), Smart Belamia (1), Sixtus (1), Taty (1), Toreador (1), Wilson (1), ZR06924 (1)
	Sowing period	From 22/03 to 17/04
Application	Number and interval	2 applications (8 trials - HU and SK) - 8-15 days interval 3 applications (10 trials - PL and DE) - 7-21 days interval
	Crop stage (BBCH) at application	A: BBCH 10-16 B: BBCH 12-33 C: BBCH 14-19
	Timing	Post-emergence of the crop
	Equipment	Experimental plot sprayers with a boom and several nozzles
	Spray volumes	200-300 L/ha (18 trials)
	Test product rates	Polish trials: 0.6 and 1.2 L/ha (6 trials) Hungarian and Slovakian trials: 1.0 L/ha and 2.0 L/ha (8 trials) German trials: 0.66 and 1.32 L/ha (4 trials)
	T°C / Humidity	5-28 °C / 30-95%
Assessment	Assessment types	<ul style="list-style-type: none"> - Phytotoxicity as % of total leaf area affected by symptom where 0% = no phyto and 100% = crop destroyed - Crop vigour as % in comparison with the untreated, where 100% = the most vigorous plot within the trial area - Ground cover of the crop (%) <u>At harvest:</u> <ul style="list-style-type: none"> - Fresh root weight (kg) - per harvested plot - Stand reduction (%) where 0% = no difference with the untreated check - Yield (t/ha) - per harvested plot - Sugar content in roots (%) and sugar yield (T/ha) - per harvested plot - Sodium content in roots (mmol/100g) - Potassium content in roots (mmol/100g) - Nitrogen content in roots (mmol/100g)
	Statistical analysis	Data were then analysed using a two-way ANOVA on untransformed or transformed data. The probability of non-significant differences occurring between treatment means is calculated as the F probability value p(F). Student-Newman-Keuls multiple comparison test was applied to separate any significant treatment differences that may be implied by the ANOVA and these are indicated by a letter: treatment means with at least one letter in common are not significantly different according to the test initiated at the 95% confidence level.
	Assessment dates	0; 15; 30 and 45 days after last application, BBCH 39 and at harvest
Other information	Field / greenhouse	Field (18 trials)
	Weeds	Weed free conditions (18 trials)

Standard methods Standards followed

The following EPPO guidelines were followed:

PP 1/135(4)	Phytotoxicity assessment
PP 1/152(4)	Design and analysis of efficacy evaluation trials
PP 1/181(4)	Conduct and reporting of efficacy evaluation trials including GEP
PP 1/225(2)	Minimum effective dose
PP 1/52(3)	Weeds in sugar and fodder beet and industrial chicory

Treatments

AG-E1-500 SC1 was applied at N rate (*i.e.* a total dose rate of 1.8 L/ha in Polish trials and 2.0 L/ha in the Hungarian, Slovakian and German trials) and at 2N rate (*i.e.* a total dose rate of 3.6 L/ha in Polish trials and 4.0 L/ha in the Hungarian, Slovakian and German trials). The standard ethofumesate product was also applied at N and 2N rates. Details of the treatments are given in the following table (for more details also see Table 3.4-2).

Table 3.4-5: Treatments applied in the selectivity trials

Treatment	Active substances	Product name	Rate	Timing
North-East EPPO zone				
Test product N rate	Ethofumesate 500 g/L	AG-E1-500 SC1	0.6 L/ha	ABC
Test product 2N rate	Ethofumesate 500 g/L	AG-E1-500 SC1	1.2 L/ha	ABC
Tank mix N rate	Ethofumesate 500 g/L Metamitron + quinmerac 525+40 g/L Rapeseed oil fatty acid methyl esters 80%	AG-E1-500 SC1 GOLTIX TITAN 565 SC ATPOLAN BIO 80 EC ⁽¹⁾	0.5 L/ha 1.5 L/ha 1.0 L/ha	ABC
Tank mix 2N rate	Ethofumesate 500 g/L Metamitron + quinmerac 525+40 g/L Rapeseed oil fatty acid methyl esters 80%	AG-E1-500 SC1 GOLTIX TITAN 565 SC ATPOLAN BIO 80 EC ⁽¹⁾	1.0 L/ha 3.0 L/ha 2.0 L/ha	ABC
Standard N rate	Metamitron + ethofumesate 350+150 g/L	FSG 01095 H ⁽²⁾	2.0 L/ha	ABC
Standard 2N rate	Metamitron + ethofumesate 350+150 g/L	FSG 01095 H ⁽²⁾	4.0 L/ha	ABC
South-East EPPO zone				
Test product N rate	Ethofumesate 500 g/L	AG-E1-500 SC1	1.0 L/ha	AB
Test product 2N rate	Ethofumesate 500 g/L	AG-E1-500 SC1	2.0 L/ha	AB
Standard N rate	Metamitron + ethofumesate 350+150 g/L	FSG 01095 H ⁽³⁾	2.0 L/ha	AB
Standard 2N rate	Metamitron + ethofumesate 350+150 g/L	FSG 01095 H ⁽³⁾	4.0 L/ha	AB
Standard N rate	Ethofumesate + phenmedipham + desmedipham 200 + 100 + 100 g/L	BELVEDERE FORTE ⁽⁴⁾	1.0 L/ha	AB
Standard 2N rate	Ethofumesate + phenmedipham + desmedipham 200 + 100 + 100 g/L	BELVEDERE FORTE ⁽⁴⁾	2.0 L/ha	AB
Maritime EPPO zone				
Test product N rate	Ethofumesate 500 g/L	AG-E1-500 SC1	0.66 L/ha	ABC
Test product 2N rate	Ethofumesate 500 g/L	AG-E1-500 SC1	1.32 L/ha	ABC
Standard N rate	Metamitron + ethofumesate 350+150 g/L	FSG 01095 H ⁽⁵⁾	2.0 L/ha	ABC
Standard 2N rate	Metamitron + ethofumesate 350+150 g/L	FSG 01095 H ⁽⁵⁾	4.0 L/ha	ABC
In trial DE20HSBEAVA600A, the tank mix was also tested :				
Tank-mix N rate	Ethofumesate 500 g/L Metamitron + quinmerac 525+40 g/L Rapeseed oil fatty acid methyl esters 80%	AG-E1-500 SC1 GOLTIX TITAN 565 SC ATPOLAN BIO 80 EC ⁽¹⁾	0.5 L/ha 1.5 L/ha 1.0 L/ha	ABC
Tank-mix 2N rate	Ethofumesate 500 g/L Metamitron + quinmerac 525+40 g/L	AG-E1-500 SC1 GOLTIX TITAN 565 SC	1.0 L/ha 3.0 L/ha	ABC

	Rapeseed oil fatty acid methyl esters 80%	ATPOLAN BIO 80 EC ⁽¹⁾	2.0 L/ha	
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⁽¹⁾ Adjuvant / ⁽²⁾ = TORERO 500 SC, zonal/local standard in Poland / ⁽³⁾ = TWISTER, zonal/local standard in Slovakia / ⁽⁴⁾ Local standard in Hungary / ⁽⁵⁾ = GOLTIX SUPER, zonal/local standard in Germany

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

➤ Results for North-East EPPO zone

- *Selectivity trials - 6 Polish trials:*

AG-E1-500 SC1 was applied up to 3*1.2 L/ha (2N rate in Poland) in 6 selectivity trials implemented in 2019 on the following crop varieties:

Jagoda	Jagiellon	Kujavia	Mazur	Ozon	Panorma
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The results are presented in the following table.

Table 3.4-6: General phytotoxicity of AG-E1-500 SC1 in the selectivity trials - North-East EPPO zone - Summary table

Number of trials with...		AG-E1-500 SC1		Standard product ⁽¹⁾		Tank-mix ⁽²⁾	
		N (3*0.6 L/ha)	2N (3*1.2 L/ha)	N	2N	N	2N
Maximum of phytotoxicity recorded during the trials	0%	6/6	6/6	6/6	6/6	6/6	6/6
	> 0% to 5%	0/6	0/6	0/6	0/6	0/6	0/6
	> 5% to 10%	0/6	0/6	0/6	0/6	0/6	0/6
	> 10% to 15%	0/6	0/6	0/6	0/6	0/6	0/6
	> 15%	0/6	0/6	0/6	0/6	0/6	0/6
Level of symptoms at the last assessments	0%	6/6	6/6	6/6	6/6	6/6	6/6
	> 0% to 5%	0/6	0/6	0/6	0/6	0/6	0/6
	> 5% to 10%	0/6	0/6	0/6	0/6	0/6	0/6
	> 10% to 15%	0/6	0/6	0/6	0/6	0/6	0/6
	> 15%	0/6	0/6	0/6	0/6	0/6	0/6

⁽¹⁾ FSG 01095 H = TORERO 500 SC (metamitron 350 g/L + ethofumesate 150 g/L) at 2.0 L/ha and 4.0 L/ha

⁽²⁾ [AG-E1-500 SC1 + GOLTIX TITAN 565 SC + ATPOLAN BIO 80 EC] at 0.5 + 1.5+ 1.0 L/ha and 1.0 + 3.0 + 2.0 L/ha

No symptoms of phytotoxicity and no loss of crop vigor were observed in any of the 6 selectivity trials, at any assessment date and for any treatment.

- *Efficacy trials - 10 Polish trials:*

AG-E1-500 SC1 was applied up to 3*0.6 L/ha (N rate for Poland) in 10 trials efficacy implemented in 2019 and 2020 on the following crop varieties:

BTS 6430	Danzel	Gracjana	Kujavia	Lavenda KWS
Leandrus	Pacific	Pikador	Silesja	Vanilla

The results are presented in the following table.

Table 3.4-7: General phytotoxicity of AG-E1-500 SC1 in the efficacy trials - North-East EPPO zone - Summary table

Number of trials with...		AG-E1-500 SC1 N (3*0.6 L/ha)	Zonal standard ⁽¹⁾ N	Local standard ⁽²⁾ N	Tank-mix ⁽³⁾ N
Maximum of phytotoxicity recorded during the trials	0%	10/10	8/10	6/6	8/10
	> 0% to 5%	0/10	0/10	0/6	0/10
	> 5% to 10%	0/10	1/10	0/6	1/10
	> 10% to 15%	0/10	1/10	0/6	1/10
	> 15%	0/10	0/10	0/6	0/10
Level of symptoms at the last assessments	0%	10/10	10/10	6/6	10/10
	> 0% to 5%	0/10	0/10	0/6	0/10
	> 5% to 10%	0/10	0/10	0/6	0/10
	> 10% to 15%	0/10	0/10	0/6	0/10
	> 15%	0/10	0/10	0/6	0/10

⁽¹⁾ FSG 01095 H = TORERO 500 SC at 3*2.0 L/ha

⁽²⁾ [POWERTWIN 400 SC + adjuvant Olejan 85 EC] at 3*[1.0 L/ha + 1.5 L/ha]

⁽³⁾ [AG-E1-500 SC1 + GOLTIX TITAN 565 SC + ATPOLAN BIO 80 EC] at 0.5 + 1.5+ 1.0 L/ha

No phytotoxicity symptoms were observed with AG-E1-500 SC1 applied solo at 3*0.6 L/ha. Acceptable (<15%) and transient phytotoxicity symptoms were observed in 2 out of 10 trials with the tank-mix [GOLTIX TITAN 565 SC + AG-E1-500 SC1] and the zonal standard TORERO 500 SC (in each case of the magnitude 6,5-12,5%, plant stunting). In both trials, the phytotoxicity symptoms observed with both treatments were similar and had disappeared at the end of the trials.

➤ Results for South-East EPPO zone

- Selectivity trials - 4 Hungarian trials and 4 Slovakian trials:

AG-E1-500 SC1 was applied up to 2*2.0 L/ha (2N rate in Hungary and Slovakia) in 8 selectivity trials implemented in 2019 on the following crop varieties:

Antek	Gundula	Maribo	Python	Smart Belamia
Sixtus	Tatry	Toreador		

The results are presented in the following table.

Table 3.4-8: General phytotoxicity of AG-E1-500 SC1 in the selectivity trials - South-East EPPO zone - Summary table

Number of trials with...		AG-E1-500 SC1		Standard product ⁽¹⁾	
		N (2*1.0 L/ha)	2N (2*2.0 L/ha)	N	2N
Maximum of phytotoxicity recorded during the trials	0%	7/8	6/8	7/8	6/8
	> 0% to 5%	1/8	1/8	1/8	1/8
	> 5% to 10%	0/8	1/8	0/8	0/8
	> 10% to 15%	0/8	0/8	0/8	1/8
	> 15%	0/8	0/8	0/8	0/8
Level of symptoms at the last assessments	0%	8/8	8/8	8/8	8/8
	> 0% to 5%	0/8	0/8	0/8	0/8
	> 5% to 10%	0/8	0/8	0/8	0/8
	> 10% to 15%	0/8	0/8	0/8	0/8
	> 15%	0/8	0/8	0/8	0/8

⁽¹⁾ FSG 01095 H = TWISTER (metamitron 350 g/L + ethofumesate 150 g/L) at 2.0 L/ha and 4.0 L/ha in 4 Slovakian trials or BELVEDERE FORTE (ethofumesate 200 g/L + phenmedipham 100 g/L + desmedipham 100 g/L) at 1.0 L/ha and 2.0 L/ha in 4 Hungarian trials

Slight and transient phytotoxicity symptoms were observed in 2 out of 8 selectivity trials, especially with the 2N rate of AG-E1-500 SC1 at 14 DA-B. In both trials, these symptoms were equivalent or even lower than that of the zonal standard product (metamitron 350 g/L + ethofumesate 150 g/L). The symptoms had disappeared at the end of the trials and there was no negative effect on yield and quality (see next points 3.4.2 and 3.4.3).

- Efficacy trials - 7 Slovakian trials and 6 Hungarian trials:

AG-E1-500 SC1 was applied up to 2*1.0 L/ha (N rate for Hungary and Slovakia) in 13 efficacy trials implemented in 2019 and 2020 on the following crop varieties:

Balaton	Deseda	Smart Belamia	Gundula	Antek	Francia
Varios	Jagger	Sixtus	Nicola	Ondava	-

The results are presented in the following table.

Table 3.4-9: General phytotoxicity of AG-E1-500 SC1 in the efficacy trials - South-East EPPO zone - Summary table

Number of trials with...		AG-E1-500 SC1 N (2*1.0 L/ha)	Zonal standard ⁽¹⁾ N	Local standard ⁽²⁾ N	Tank-mix ⁽³⁾ N
Maximum of phytotoxicity recorded during the trials	0%	10/13	10/13	3/5	5/7
	> 0% to 5%	3/13	3/13	2/5	2/7
	> 5% to 10%	0/13	0/13	0/5	0/7
	> 10% to 15%	0/13	0/13	0/5	0/7
	> 15%	0/13	0/13	0/5	0/7
Level of symptoms at the last assessments	0%	13/13	13/13	5/5	7/7
	> 0% to 5%	0/13	0/13	0/5	0/7
	> 5% to 10%	0/13	0/13	0/5	0/7
	> 10% to 15%	0/13	0/13	0/5	0/7
	> 15%	0/13	0/13	0/5	0/7

(1) FSG 01095 H = TWISTER = GOLTIX SUPER at 2*2.0 L/ha / (2) BELVEDERE FORTE at 2*1.0 L/ha or GOLTIX TITAN at 2*2.0 L/ha

(3) [GOLTIX TITAN + AG-E1-500-SC1] at 2*[2.0 + 1.0 L/ha]

Very slight and transient phytotoxicity symptoms were observed in 3 out of 13 efficacy trials with the N rate of AG-E1-500 SC1 at 15 DA-A (0,5-1,3%, PHYGEN) and 15 DA-B (1,0-5,3%, PHYGEN). In all trials, these symptoms were equivalent to those of the reference products. The symptoms had disappeared at the end of the trials. A slight loss of crop vigour was observed in these 3 trials but was no longer observed when the phytotoxicity symptoms disappeared.

➤ Complementary results of the Maritime EPPO zone

- Selectivity trials - 4 German trials:

AG-E1-500 SC1 was applied up to 3*1.32 L/ha (2N rate in Germany) in 4 selectivity trials implemented in 2019 and 2020 on the following crop varieties:

BTS 6000	Fiorella	Wilson	ZR06924
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The results are presented in the following table.

Table 3.4-10: General phytotoxicity of AG-E1-500 SC1 in the selectivity trials - Maritime EPPO zone - Summary table

Number of trials with...		AG-E1-500 SC1		Standard product ⁽¹⁾		Tank-mix ⁽²⁾	
		N (3*0.66 L/ha)	2N (3*1.32 L/ha)	N	2N	N	2N
Maximum of phytotoxicity recorded during the trials	0%	4/4	4/4	4/4	4/4	1/1	1/1
	> 0% to 5%	0/4	0/4	0/4	0/4	0/1	0/1
	> 5% to 10%	0/4	0/4	0/4	0/4	0/1	0/1
	> 10% to 15%	0/4	0/4	0/4	0/4	0/1	0/1
	> 15%	0/4	0/4	0/4	0/4	0/1	0/1
Level of symptoms at the last assessments	0%	4/4	4/4	4/4	4/4	1/1	1/1
	> 0% to 5%	0/4	0/4	0/4	0/4	0/1	0/1
	> 5% to 10%	0/4	0/4	0/4	0/4	0/1	0/1
	> 10% to 15%	0/4	0/4	0/4	0/4	0/1	0/1
	> 15%	0/4	0/4	0/4	0/4	0/1	0/1

(1) FSG 01095 H = GOLTIX SUPER (metamitron 350 g/L + ethofumesate 150 g/L) at 2.0 L/ha and 4.0 L/ha

(2) [AG-E1-500 SC1 + GOLTIX TITAN 565 SC + ATPOLAN BIO 80 EC] at 0.5 +1.5 +1.0 L/ha and 1.0 + 3.0 + 2.0 L/ha

No symptoms of phytotoxicity and no loss of crop vigor were observed in any of the 4 selectivity trials, at any assessment date and for any treatment.

- Efficacy trials – 4 Czech and 2 German trials:

AG-E1-500 SC1 was applied up to 3*0.66 L/ha (N rate for the Czech Republic and Germany) in 6 trials efficacy implemented in 2019 and 2020 on the following crop varieties:

BTS8840	Danicia	Jagger	Kaplan	Lunella	Smart Renja KWS
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The results are presented in the following table.

Table 3.4-11: General phytotoxicity of AG-E1-500 SC1 in the efficacy trials - Maritime EPPO zone - Summary table

Number of trials with...		AG-E1-500 SC1 N (3*0.66 L/ha)	Zonal standard ⁽¹⁾ N
Maximum of phytotoxicity recorded during the trials	0%	5/6	5/6
	> 0% to 5%	1/6	0/6
	> 5% to 10%	0/6	1/6
	> 10% to 15%	0/6	0/6
	> 15%	0/6	0/6
Level of symptoms at the last assessments	0%	6/6	6/6
	> 0% to 5%	0/6	0/6
	> 5% to 10%	0/6	0/6
	> 10% to 15%	0/6	0/6
	> 15%	0/6	0/6

⁽¹⁾ FSG 01095 H = GOLTIX SUPER at 3*2.0 L/ha

Very slight (<5%) and transient phytotoxicity symptoms were observed in 1 out of 6 trials with AG-E1-500 SC1 at 3*0.66 L/ha whereas the standard product induced slight symptoms (7%). The symptoms of both treatments had disappeared at the end of the trial.

Conclusion of selectivity for the North-East EPPO zone:

According to the results of 6 selectivity trials and 10 efficacy trials carried out in the North-East EPPO zone (Poland) in 2019 and 2020, AG-E1-500 SC1 applied on sugar beet up to 0.6 L/ha and maximum 3 times per season (*i.e.* a total rate of 1.8 L/ha) is safe to sugar beet, and by extrapolation to fodder beets.

According to the results of 4 selectivity trials and 6 efficacy trials carried out in the Maritime EPPO zone (Germany and Czech Republic) in 2019 and 2020, AG-E1-500 SC1 applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (*i.e.* a total rate of 2.0 L/ha) is safe to sugar beet, and by extrapolation to fodder beets.

According to the results of 6 selectivity trials and 10 efficacy trials carried out in the North-East EPPO zone (Poland) in 2019 and 2020, AG-E1-500 SC1 applied at 3 times at 0.5 L/ha in tank-mix with GOLTIX TITAN and an oil-based adjuvant, is safe to sugar beet, and by extrapolation to fodder beets. Results of 1 selectivity trial carried out in the Maritime EPPO zone (Germany) in 2020 led to the same conclusion.

Regarding beet crops, the agronomic conditions and cultural practices in Germany and Czech Republic (Maritime EPPO zone) are very close to what is encountered in Poland (North-East EPPO zone). Moreover, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Germany and Czech Republic are considered as supportive to evaluate the selectivity of AG-E1-500 SC1 on sugar and fodder beet in Poland.

Conclusion of selectivity for the South-East EPPO zone:

According to the results of 8 selectivity trials and 13 efficacy trials carried out in the South-East EPPO zone in 2019 and 2020, AG-E1-500 SC1 applied on sugar beet up to 1.0 L/ha and maximum 2 times per season (*i.e.* a total rate of 2.0 L/ha) is safe to sugar beet, and by extrapolation to fodder beets.

According to the results of 6 selectivity trials and 10 efficacy trials carried out in the North-East EPPO zone in 2019 and 2020, AG-E1-500 SC1 applied on sugar beet up to 0.6 L/ha and maximum 3 times per season (*i.e.* a total rate of 1.8 L/ha) is safe to sugar beet, and by extrapolation to fodder beets.

According to the results of 4 selectivity trials carried out in the Maritime EPPO zone (Germany) in 2019 and 2020, AG-E1-500 SC1 applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (*i.e.* a total rate of 2.0 L/ha) is safe to sugar beet, and by extrapolation to fodder beets.

Regarding beet crops, the agronomic conditions and cultural practices in Poland (North-East EPPO zone), Germany and Czech Republic (Maritime EPPO zone) are close to what is encountered in the South-East zone. Moreover, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Poland, Germany and Czech Republic are considered as

supportive to evaluate the selectivity of AG-E1-500 SC1 on sugar and fodder beet in Hungary and Slovakia. In addition, the test product AG-E1-500 SC1 was registered during many years at 2*1.0 L/ha (*i.e.* a total dose rate of 2.0 L/ha) in Slovakia and Poland and at 1*2.0 L/ha in Germany, and no phytotoxicity was ever reported.

zRMS comments:

No symptoms of phytotoxicity were observed in selectivity trials in the NE zone (where the single dose rate is 0.6 L/ha), and only some transient symptoms have been reported from the SE zone (selectivity) trials (where the single dose rate is 1.0 L/ha), predominantly in plots treated with 2N dose rates.

In efficacy trials, the reports of phytotoxicity (in 2 out of 8 trials in PL and in 3 out of 8 trials - in the SE zone) are restricted to 1N dose rates of both test and the reference items, suggesting the underlying reasons related to external factors rather than overdosing, both in the NE and the SE zone. Only in 2 NE trials the intensity of symptoms (plant stunting) exceeded 10% at 15 DA-B. The symptoms` intensity was comparable to that observed in plots treated with zonal and local standards, and they receded by the time of the last assessments.

Additionally, results of the Maritime zone selectivity (4) and efficacy (6) trials remain in agreement with the NE and SE data, and they confirm the relative safety of the test item for the beet crops, while using single dose rate of 0.66 L/ha instead of 0.60 L/ha as proposed in the NE zone. No phytotoxicity has been reported from the proper selectivity trials, and only in one case the symptoms of low intensity (<5%) were reported from a single efficacy trial.

Considered the frequency and intensity of phytotoxic symptoms, as much as the respective treatments and dose rates at which these symptoms occurred, zRMS considers that the selectivity data prove acceptable crop safety after the application of AG-E1-500 SC1 solo or in the proposed tank-mix.

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

The yield of crop was evaluated in the 18 selectivity trials.

Results for the North-East EPPO zone - 6 Polish trials, 2019:

AG-E1-500 SC1 was applied up to 3*1.2 L/ha (2N rate) in 6 selectivity trials implemented in Poland in 2019. Yield results are presented in the following table.

Table 3.4-12: Yield of sugar beet roots with AG-E1-500 SC1 applied 3 times - North-East EPPO zone - 6 selectivity trials

Grouping (number of trials)	Variable.	Untreated control	AG-E1-500 SC1		Tank-mix ⁽¹⁾		Zonal/local standard ⁽²⁾	
			N 3*0.6 L/ha	2N 3*1.2 L/ha	N	2N	N	2N
Yield (T/ha) Yield (% untreated)*								
Mean yield (n=6)	Mean (Min-Max)	56;9 (41.6-79.6)	100.3% (99.1-101.1)	104.0% (99.9-115.8)	100.1% (93.8-104.0)	102.6% (97.5-115.6)	103.3% (99.5-117.3)	101.9% (97.4-111.8)

⁽¹⁾ [AG-E1-500 SC1 + GOLTIX TITAN 565 SC + ATPOLAN BIO 80 EC] at 0.5 +1.5+1.0 L/ha and 1.0 + 3.0 + 2.0 L/ha

⁽²⁾ FSG 01095 H = TORERO 500 SC (metamitron 350 g/L + ethofumesate 150 g/L) at 2.0 L/ha and 4.0 L/ha

*Values in the untreated control are expressed in T/ha; values in the treated plots are expressed % untreated with untreated =100%.

AG-E1-500 SC1 at N and 2N dose rates showed yield results comparable to that of the untreated control and the zonal standard (metamitron 350 g/L + ethofumesate 150 g/L). The differences were not statistically significant in any trial.

Results for South-East EPPO zone - 4 Hungarian and 4 Slovakian trials, 2019:

AG-E1-500 SC1 was applied up to 2*2.0 L/ha (2N rate) in 8 selectivity trials implemented in 2019. Yield results are presented in the following table.

Table 3.4-13: Yield of sugar beet roots with AG-E1-500 SC1 applied 2 times - South-East EPPO zone - 8 selectivity trials

selectivity trials								
Grouping (number of trials)	Variable	Untreated control	AG-E1-500 SC1		Zonal/local standard ⁽¹⁾		Local standard ⁽²⁾	
			N 2*1.0 L/ha	2N 2*2.0 L/ha	N	2N	N	2N
Yield (T/ha) Yield (% untreated)*								
Comparison with FSG 01095 H (n=4)	Mean (Min-Max)	52.2 (35.2-74.8)	102.3% (99.9-107.1)	103.4% (99.8-109.2)	104.3% (99.9-115.0)	102.4% (99.8-109.6)	- -	- -
Comparison with BELVEDERE FORTE (n=4)	Mean (Min-Max)	74.2 (54.3-107.6)	98.8% (96.4-102.4)	101.2% (94.3-114.0)	- -	- -	100.5% (94.2-112.7)	107.1% (95.9-125.1)
Comparison with the untreated (n=8)	Mean (Min-Max)	63.2 (35.2-107.6)	100.6% (96.4-107.1)	102.3% (94.3-114.0)	- -	- -	- -	- -

⁽¹⁾ FSG 01095 H = TWISTER (metamitron 350 g/L + ethofumesate 150 g/L) at 2.0 L/ha and 4.0 L/ha

⁽²⁾ BELVEDERE FORTE (ethofumesate 200 g/L + phenmedipham 100 g/L + desmedipham 100 g/L at 1.0 L/ha and 2.0 L/ha

*Values in the untreated control are expressed in T/ha; values in the treated plots are expressed % untreated with untreated =100%.

AG-E1-500 SC1 at N and 2N rates showed yield results comparable to that of the untreated control and the standard products. The differences were not statistically significant in any trial.

Complementary results in Maritime EPPO zone - 4 German trials, 2019-2020:

AG-E1-500 SC1 was applied up to 3*1.32 L/ha (2N rate in Germany) in 4 selectivity trials implemented in 2019 and 2020. Yield results are presented in the following table.

Table 3.4-14: Yield of sugar beet roots with AG-E1-500 SC1 applied 3 times - Maritime EPPO zone 2019-2020 - 4 selectivity trials

Trial ID	Country	Crop variety	Days after last application	Yield of sugar beet roots						
				Untreated control	AG-E1-500 SC1		Zonal/local standard ⁽¹⁾		Tank-mix ⁽²⁾	
					N (3*0.66 L/ha)	2N (3*1.32 L/ha)	N	2N	N	2N
Yield (T/ha) - Yield (% untreated)*										
DE20HSBE AVA600A	DE	Fiorella	159 DA-C	47.7 a 100.0%	46.2 a 97.1%	43.8 a 91.8%	47.2 a 99.1%	45.5 a 95.3%	47.0 a 98.6%	44.9 a 94.3%
DE19HSBE AVA602A	DE	ZR06935	135 DA-C	77.6 a 100.0%	91.9 a 123.7%	86.8 a 113.4%	83.3 a 108.0%	77.9 a 101.8%	-	-
DE20HSBE AVA605A	DE	BTS 6000	143 DA-C	101.6 a 100.0%	107.5 a 105.9%	107.1 a 105.5%	108.9 a 107.3%	108.7 a 107.1%	-	-
DE20HSBE AVA605B	DE	Wilson	146 DA-C	90.7 a 100.0%	98.2 a 112.4%	96.1 a 107.7%	100.5 a 113.0%	87.0 a 97.9%	-	-
Comparison with FSG 01095 H (n=4)			Mean (Min-Max)	79.4 (47.7-101.6)	109.8% (97.1-123.7)	104.6% (91.8-113.4)	106.9% (99.1-113.0)	100.5% (95.8-107.1)	-	-
Comparison with the tank-mix (n=1)			Mean (Min-Max)	47.7	97.1%	91.8%	99.1%	95.3%	98.6% -	94.3% -

⁽¹⁾ FSG 01095 H = GOLTIX SUPER (metamitron 350 g/L + ethofumesate 150 g/L) at 2.0 L/ha and 4.0 L/ha

⁽²⁾ [AG-E1-500 SC1 + GOLTIX TITAN 565 SC + ATPOLAN BIO 80 EC] at 0.5 + 1.5 + 1.0 L/ha and 1.0 + 3.0 + 2.0 L/ha

*Values in the untreated control are expressed in T/ha; values in the treated plots are expressed %untreated with untreated =100%.

AG-E1-500 SC1 at N and 2N rates showed yield results comparable to that of the untreated control and the standard product. The differences were not statistically significant in any trial.

Conclusion on the effect on yield for the North-East EPPO zone:

According to the results of 6 selectivity trials carried out in the North-East EPPO zone (Poland) in 2019, AG-E1-500 SC1 applied on sugar beet up to 0.6 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1.8 L/ha) has no negative impact on the yield of the treated beets.

According to the results of 4 selectivity trials carried out in the Maritime EPPO zone (Germany) in 2019 and 2020, AG-E1-500 SC1 applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 2.0 L/ha) has no negative impact on the yield of the treated beets.

According to the results of 6 selectivity trials carried out in the North-East EPPO zone (Poland) in 2019 and 2020, AG-E1-500 SC1 applied at 3 times at 0.5 L/ha in tank-mix with GOLTIX TITAN and an oil-based adjuvant has no negative impact on the yield of the treated crop. Results of 1 selectivity trial carried out in the Maritime EPPO zone (Germany) in 2020 led to the same conclusion.

Regarding beet crops, the agronomic conditions and cultural practices in Germany and Czech Republic (Maritime EPPO zone) are very close to what is encountered in Poland (North-East EPPO zone). Moreover, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Germany are considered as supportive to evaluate the impact of AG-E1-500 SC1 on the yield of treated beets in Poland.

Conclusion on the effect on yield for the South-East EPPO zone:

According to the results of 8 selectivity trials carried out in the South-East EPPO zone (Hungary and Slovakia) in 2019, AG-E1-500 SC1 applied on sugar beet up to 1.0 L/ha and maximum 2 times per season (corresponding to a total dose rate of 2.0 L/ha) has no negative impact on the yield of the treated beets.

According to the results of 6 selectivity trials carried out in the North-East EPPO zone (Poland) in 2019, AG-E1-500 SC1 applied on sugar beet up to 0.6 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1.8 L/ha) has no negative impact on the yield of the treated beets.

According to the results of 4 selectivity trials carried out in the Maritime EPPO zone (Germany) in 2019 and 2020, AG-E1-500 SC1 applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 2.0 L/ha) has no negative impact on the yield of the treated beets.

Regarding beet crops, the agronomic conditions and cultural practices in Poland (North-East EPPO zone) and Germany (Maritime EPPO zone) are close to what is encountered in the South-East zone. Moreover, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Poland and Germany are considered as supportive to evaluate the impact of AG-E1-500 SC1 on the yield of treated beets in Hungary and Slovakia. In addition, the test product AG-E1-500 SC1 was registered during many years at 2*1.0 L/ha (*i.e.* a total dose rate of 2.0 L/ha) in Slovakia and Poland and at 1*2.0 L/ha in Germany, and no phytotoxicity was ever reported.

zRMS comments:

The applicant's conclusions concerning the test item's effect on yield are correct: both after the solo application and the tank-mix application with the proposed partner herbicide, no statistically significant differences were observed between the experimental treatments, therefore no negative effect on yield is expected.

However, while these conclusions are valid separately for the respective EPPO zones, the applicant's considerations on the homogenous climatic conditions across Germany, Poland and the South-East zone are somewhat out of place. The cMSs Hungary and Slovakia may decide on their own to what extent the selectivity trials from Germany and Poland may be indeed supportive for AG-E1-500 SC1 selectivity evaluation in their own regions.

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

The following quality parameters of the treated roots were evaluated in the 18 selectivity trials: sugar content (%), sugar yield (T/ha), sodium content, potassium content and amino-nitrogen content.

Results for North-East EPPO zone - 6 Polish trials, 2019:

AG-E1-500 SC1 was applied up to 3*1.2 L/ha (2N rate in Poland) in 6 selectivity trials implemented in 2019. Quality results are presented in the following table.

Table 3.4-15: Quality parameters of treated roots - North-East EPPO zone - 6 selectivity trials

Grouping (number of trials)	Variable	Untreated control	AG-E1-500 SC1		Tank-mix ⁽¹⁾		Zonal/local standard ⁽²⁾	
			N	2N	N	2N	N	2N
			3*0.6 L/ha	3*1.2 L/ha	3*2.0 L/ha	3*4.0 L/ha	3*2.0 L/ha	3*4.0 L/ha
Sugar content (%)								
Mean sugar content n=6	Mean (Min-Max)	17.69 (16.57-19.17)	17.65 (16.63-19.18)	17.80 (16.80-19.41)	17.97 (17.02-19.52)	17.82 (16.60-19.67)	17.81 (16.81-19.65)	17.67 (16.29-18.98)
Sugar yield (T/ha) <i>Sugar yield (% of untreated)*</i>								
Mean sugar yield n=6	Mean (Min-Max)	12.7 (7.3-17.6)	100.2% (96.9-102.0)	101.2% (99.7-103.5)	102.1% (100.8-105.4)	101.2% (97.8-103.9)	101.0% (97.7-103.3)	102.3% (98.5-106.0)
Sodium content (mmol per 1000g)								
Mean sodium content n=6	Mean (Min-Max)	4.4 (3.6-5.8)	4.4 (3.2-5.9)	4.3 (2.9-5.6)	4.3 (2.9-5.8)	4.3 (2.9-6.2)	4.3 (2.9-5.4)	4.6 (3.1-6.7)
Potassium content (mmol per 1000g)								
Mean potassium content n=6	Mean (Min-Max)	40.0 (33.2-43.9)	40.9 (33.2-44.4)	39.7 (33.2-44.0)	40.0 (33.5-44.7)	41.0 (33.4-49.7)	40.6 (33.3-43.9)	40.6 (33.6-43.9)
Amino-nitrogen content (mmol per 1000g)								
Mean amino-nitrogen content n=6	Mean (Min-Max)	20.6 (16.8-26.1)	22.6 (17.0-29.5)	21.5 (16.8-30.3)	21.8 (17.0-31.5)	23.3 (17.4-35.6)	22.4 (16.7-35.4)	20.7 (14.7-28.4)

⁽¹⁾ [AG-E1-500 SC1 + GOLTIX TITAN 565 SC + ATPOLAN BIO 80 EC] at 0.5 + 1.5 + 1.0 L/ha and 1.0 + 3.0 + 2.0 L/ha

⁽²⁾ FSG 01095 H = TORERO 500 SC (metamitron 350 g/L + ethofumesate 150 g/L) at 2.0 L/ha and 4.0 L/ha

*Values in the untreated control are expressed in T/ha; values in the treated plots are expressed % untreated with untreated =100%.

AG-E1-500 SC1 at N and 2N applied solo or in tank-mix showed quality parameters of roots comparable to that of the untreated control and the zonal standard product. The differences were not statistically significant in any trial.

Results for South-East EPPO zone - 4 Hungarian and 4 Slovakian trials, 2019:

AG-E1-500 SC1 was applied up to 2*2.0 L/ha (2N rate in Hungary and Slovakia) in 8 selectivity trials implemented in 2019. Quality results are presented in the following table.

Table 3.4-16: Quality parameters of treated roots - South-East EPPO zone

Grouping (number of trials)	Variable	Untreated control	AG-E1-500 SC1		Zonal/local standard ⁽¹⁾		Local standard ⁽²⁾	
			N	2N	N	2N	N	2N
			2*1.0 L/ha	2*2.0 L/ha	2*2.0 L/ha	2*4.0 L/ha	2*1.0 L/ha	2*2.0 L/ha
Sugar content (%)								
Comparison with FSG 01095 H (n=4)	Mean (Min-Max)	18.04 (17.10-19.15)	18.12 (17.80-18.83)	18.31 (17.60-19.88)	18.04 (17.30-19.03)	18.15 (17.70-19.15)	-	-
Comparison with BELVEDERE FORTE (n=4)	Mean (Min-Max)	16.92 (14.93-19.72)	16.95 (14.49-19.93)	17.17 (15.36-19.89)	-	-	16.98 (15.00-19.64)	16.79 (14.57-19.70)
Comparison with the untreated (n=8)	Mean (Min-Max)	17.48 (14.93-19.72)	17.53 (14.49-19.93)	17.74 (15.36-19.89)	-	-	-	-
Sugar yield (T/ha) -Sugar yield (%untreated)*								
Comparison with FSG 01095 H (n=4)	Mean (Min-Max)	9.31 (6.75-12.80)	102.8% (99.8-106.4)	105.2% (99.4-114.3)	104.4% (99.6-114.5)	103.0% (99.2-109.7)	-	-
Comparison with BELVEDERE FORTE (n=4)	Mean (Min-Max)	13.19 (10.70-16.04)	99.0% (94.6-103.5)	102.9% (96.5-112.6)	-	-	101.2% (95.6-112.5)	106.3% (97.4-122.9)
Comparison with the untreated (n=8)	Mean (Min-Max)	11.25 (6.75-16.04)	100.9% (94.6-106.4)	104.0% (96.5-114.3)	-	-	-	-
Sodium content (mmol/100g)								
Comparison with FSG 01095 H (n=4)	Mean (Min-Max)	0.6 (0.3-0.9)	0.6 (0.3-0.9)	0.5 (0.3-0.8)	0.6 (0.3-0.9)	0.6 (0.3-0.9)	-	-
Comparison with BELVEDERE FORTE (n=4)	Mean (Min-Max)	0.8 (0.5-1.0)	0.9 (0.4-1.2)	0.9 (0.4-1.2)	-	-	0.8 (0.4-1.2)	0.9 (0.5-1.3)
Comparison with the untreated (n=8)	Mean (Min-Max)	0.7 (0.3-1.0)	0.7 (0.3-1.2)	0.7 (0.3-1.2)	-	-	-	-
Potassium content (mmol/100g)								
Comparison with FSG 01095 H (n=4)	Mean (Min-Max)	3.1 (2.6-3.6)	3.1 (2.5-3.6)	3.0 (2.3-3.6)	3.0 (2.4-3.6)	3.0 (2.5-3.6)	-	-
Comparison with BELVEDERE FORTE (n=4)	Mean (Min-Max)	3.9 (3.2-4.7)	3.8 (3.1-4.7)	3.9 (3.0-4.7)	-	-	3.8 (3.0-4.7)	3.8 (3.0-4.7)
Comparison with the untreated (n=8)	Mean (Min-Max)	3.5 (2.6-4.7)	3.4 (2.5-4.7)	3.4 (2.3-4.7)	-	-	-	-
Amino-nitrogen content (mmol/100g)								
Comparison with FSG 01095 H (n=4)	Mean (Min-Max)	1.1 (0.9-1.2)	1.0 (0.8-1.2)	1.0 (0.8-1.2)	1.0 (0.8-1.2)	1.0 (0.9-1.2)	-	-
Comparison with BELVEDERE FORTE (n=4)	Mean (Min-Max)	3.0 (1.8-6.0)	3.1 (1.9-6.1)	3.0 (1.9-5.8)	-	-	3.1 (1.9-6.2)	3.0 (2.1-5.7)
Comparison with the untreated (n=8)	Mean (Min-Max)	2.1 (0.9-6.0)	2.1 (0.8-6.1)	2.0 (0.8-5.8)	-	-	-	-

⁽¹⁾ FSG 01095 H = TWISTER (metamitron 350 g/L + ethofumesate 150 g/L) at 2.0 L/ha and 4.0 L/ha

⁽²⁾ BELVEDERE FORTE (ethofumesate 200 g/L + phenmedipham 100 g/L + desmedipham 100 g/L at 1.0 L/ha and 2.0 L/ha

*Values in the untreated control are expressed in T/ha; values in the treated plots are expressed %untreated with untreated =100%.

AG-E1-500 SC1 at N and 2N showed quality parameters of roots comparable to that of the untreated control and the zonal standard product. The differences were not statistically significant in any trial.

Complementary results in Maritime EPPO zone - 4 German trials, 2019-2020:

AG-E1-500 SC1 was applied up to 3*1.32 L/ha (2N rate in Germany) in 4 selectivity trials implemented in 2019 and 2020.

Quality results are presented in the following table.

Table 3.4-17: Quality parameters of treated roots - Maritime EPPO zone - 4 selectivity trials

Trial ID	Coun-try	Crop variety	Days after last applicatio-n	Untreat-ed control	AG-E1-500 SC1		Zonal/local standard ⁽¹⁾		Tank-mix ⁽²⁾	
					N 3*0.6 L/ha	2N 3*1.2 L/ha	N	2N	N	2N
Sugar content (%)										
Comparison with FSG 01095 H (n=4)			Mean (Min-Max)	16.6 (14.3-19.5)	17.0 (15.3-19.6)	17.0 (14.8-19.6)	16.9 (14.8-19.4)	16.9 (14.6-19.2)	-	-
Comparison with the tank-mix (n=1)			Mean (Min-Max)	14.3 -	15.3 -	14.8 -	14.8 -	14.6 -	15.1 -	14.6 -
Sugar yield (T/ha) - Sugar yield (% of untreated)*										
Comparison with FSG 01095 H (n=4)			Mean (Min-Max)	13.4 (6.8-17.9)	112.3% (103.7-123.4)	107.3% (95.6-114.4)	109.1% (102.6-113.7)	102.8% (96.7-116.1)	-	-
Comparison with the tank-mix (n=1)			Mean (Min-Max)	6.8 -	103.7% -	95.6% -	102.6% -	96.8% -	103.9% -	96.4% -
Sodium content (mmol per 1000g)										
Comparison with FSG 01095 H (n=4)			Mean (Min-Max)	0.5 (0.3-0.6)	0.5 (0.3-0.7)	0.5 (0.3-0.6)	0.5 (0.3-0.6)	0.5 (0.3-0.6)	-	-
Comparison with the tank-mix (n=1)			Mean (Min-Max)	0.6 -	0.6 -	0.6 -	0.6 -	0.6 -	0.6 -	0.6 -
Potassium content (mmol per 1000g)										
Comparison with FSG 01095 H (n=4)			Mean (Min-Max)	4.1 (2.7-6.1)	4.3 (3.0-6.1)	4.2 (2.8-5.9)	4.1 (2.7-5.9)	4.4 (2.7-6.9)	-	-
Comparison with the tank-mix (n=1)			Mean (Min-Max)	6.1 -	6.1 -	5.9 -	5.9 -	6.9 -	6.7 -	6.1 -
Amino-nitrogen content (mmol per 1000g)										
Comparison with FSG 01095 H (n=4)			Mean (Min-Max)	2.6 (1.5-3.9)	2.8 (1.6-4.3)	2.6 (1.5-4.3)	2.7 (1.6-4.3)	2.9 (1.8-4.9)	-	-
Comparison with the tank-mix (n=1)			Mean (Min-Max)	3.9 -	4.3 -	4.3 -	4.3 -	4.9 -	4.7 -	4.5 -

⁽¹⁾ FSG 01095 H = GOLTIX SUPER (metamitron 350 g/L + ethofumesate 150 g/L) at 2.0 L/ha and 4.0 L/ha

⁽²⁾ [AG-E1-500 SC1 + GOLTIX TITAN 565 SC + ATPOLAN BIO 80 EC] at 0.5 + 1.5 + 1.0 L/ha and 1.0 + 3.0 + 2.0 L/ha

*Values in the untreated control are expressed in T/ha; values in the treated plots are expressed %untreated with untreated =100%.

AG-E1-500 SC1 at N and 2N showed quality parameters of roots comparable to that of the untreated control and the zonal standard product. The differences were not statistically significant in any trial.

Conclusion on the effect on quality for the North-East EPPO zone:

According to the results of 6 selectivity trials carried out in the North-East EPPO zone (Poland) in 2019, AG-E1-500 SC1 applied on sugar beet up to 0.6 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1.8 L/ha) has no negative impact on the quality of the treated roots.

According to the results of 4 selectivity trials carried out in the Maritime EPPO zone (Germany) in 2019 and 2020, AG-E1-500 SC1 applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 2.0 L/ha) has no negative impact on the quality of the treated roots.

According to the results of 6 selectivity trials carried out in the North-East EPPO zone (Poland) in 2019 and 2020, AG-E1-500 SC1 applied at 3 times at 0.5 L/ha in tank-mix with GOLTIX TITAN and an oil-based adjuvant has no negative impact on the quality of the treated roots. Results of 1 selectivity trial carried out in the Maritime EPPO zone (Germany) in 2020 led to the same conclusion.

Regarding beet crops, the agronomic conditions and cultural practices in Germany and Czech Republic (Maritime EPPO zone) are very close to what is encountered in Poland (North-East EPPO zone). Moreover, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Germany are considered as supportive to evaluate the impact of AG-E1-500 SC1 on the quality of the treated roots in Poland.

Conclusion on the effect on quality for the South-East EPPO zone:

According to the results of 8 selectivity trials carried out in the South-East EPPO zone (Hungary and Slovakia) in 2019, AG-E1-500 SC1 applied on sugar beet up to 1.0 L/ha and maximum 2 times per season (corresponding to a total dose rate of 2.0 L/ha) has no negative impact on the quality of the treated roots.

According to the results of 6 selectivity trials carried out in the North-East EPPO zone (Poland) in 2019, AG-E1-500 SC1 applied on sugar beet up to 0.6 L/ha and maximum 3 times per season (corresponding to a total dose rate of 1.8 L/ha) has no negative impact on the quality of the treated roots.

According to the results of 4 selectivity trials carried out in the Maritime EPPO zone (Germany) in 2019 and 2020, AG-E1-500 SC1 applied on sugar beet up to 0.66 L/ha and maximum 3 times per season (corresponding to a total dose rate of 2.0 L/ha) has no negative impact on the quality of the treated roots.

Regarding beet crops, the agronomic conditions and cultural practices in Poland (North-East EPPO zone) and Germany (Maritime EPPO zone) are close to what is encountered in the South-East zone. Moreover, the climatic conditions at application were globally homogeneous from a climatic zone to another. Thus, complementary data from Poland and Germany are considered as supportive to evaluate the impact of AG-E1-500 SC1 on the quality of the treated roots in Hungary and Slovakia. In addition, the test product AG-E1-500 SC1 was registered during many years at 2*1.0 L/ha (*i.e.* a total dose rate of 2.0 L/ha) in Slovakia and Poland and at 1*2.0 L/ha in Germany, and no phytotoxicity was ever reported.

zRMS comments:

Five parameters were tested in altogether 14 NE+SE zones trials and in 4 Maritime zone supportive trials, in order to reveal the potential impact of AG-E1-500 SC1 application on the yield quality of sugar beet: sugar content in root, yield of sugar, and the sodium, potassium and the amine nitrogen content.

The results demonstrate statistically uniform values of the parameters tested, in all the respective trials across all the relevant treatments. Therefore no negative impact on yield quality should be expected.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Not relevant for sugar and fodder beets.

The effect of AG-E1-500 SC1 on sugar content was addressed in point 3.4.3 Effects on the quality of plants or plant products.

Comments of zRMS:

Sugar extraction from the sugar beet root is by no means transformation as defined by the EPPO guideline PP 1/243 (2) *Effects of plant protection products on transformation processes*, and fodder beet is also no subject to any transformation using microorganisms. Therefore the non-submission of data for 3.4.4 is justified.

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

Results from 29 efficacy trials and 18 selectivity trials on sugar beet showed that AG-E1-500 SC1 applied according to the recommendations up to a total of 2.0 L/ha (2*1.0 L/ha) or 1.8 L/ha (3*0.6 L/ha) is safe to sugar beets therefore no adverse effects on treated plants or plant products to be used for propagation are expected.

Comments of zRMS

Since AG-E1-500 SC1 is not intended to be applied in the seed plantations of sugar beet, no data on the effect on propagative material have been submitted, which is acceptable. On the contrary, the applicant's statement on the AG-E1-500 SC1 showing no effect on propagative material is irrelevant, as not supported by any data within the present dossier. It is also unnecessary in context of the current submission.

Summary and conclusion of point 3.4 Adverse effect on treated crop

- Results from 18 selectivity trials and 29 efficacy trials carried out in 2019 and 2020 showed that AG-E1-500 SC1 applied up to a total of 2.0 L/ha (2*1.0 L/ha) or 1.8 L/ha (3*0.6 L/ha) is safe to sugar beets, and by extrapolation to fodder beets.
- Yield results from 18 selectivity trials carried out in 2019 and 2020 showed that AG-E1-500 SC1 applied up to a total of 2.0 L/ha (2*1.0 L/ha) or 1.8 L/ha (3*0.6 L/ha) has no negative impact on the yield of the treated beets.
- Results from 18 selectivity trials carried out in 2019 and 2020 showed that AG-E1-500 SC1 applied up to a total of 2.0 L/ha (2*1.0 L/ha) or 1.8 L/ha (3*0.6 L/ha) has no negative impact on the sugar content, sugar yield, sodium content, potassium content and amino-nitrogen contents of the treated roots.
- No impact on treated plants or plant products used for propagation is expected.

Comments of zRMS:

The applicant's summary and conclusions of the 3.4. chapter are consistent with the chapter's content and valid.

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

In a total of 18 selectivity trials and 29 efficacy trials on sugar beet, AG-E1-500 SC1 demonstrated a high crop safety. The applicant implemented 3 studies evaluating the effect of AG-E1-500 SC1 on succeeding crops (2 field trials and 1 study in laboratory).

3.5.1 Impact on succeeding crops (KCP 6.5.1)

A total of 2 field trials on replacement crops and 1 study in laboratory evaluated the impact of AG-E1-500 SC1 on succeeding crops. An overview of the available field trials is provided in the table below.

Table 3.5-1: List of the field succeeding crops trials in sugar beet

EPPO zone	Country	Year	Trial ID	Testing facility	GEP or not GEP
Maritime	France	2019	FR19HUBEAVA101A	SAS Ephydia	GEP
Maritime	France	2019	FR19HUBEAVA101B	SAS Ephydia	GEP

The trials locations are illustrated on the map below.



Figure 4: Locations of the 2 replacement crops trials in France (field)

Material and methods

Details on trial methodology are summarized in the following table.

Table 3.5-2: Details on trial methodology - 2 replacement crops trials (field)

Guidelines	General guidelines	EPPO: PP 1/135(4), 1/152(4), 1/181(4), 1/207(2), CEB method No.96
	Specific guidelines	-
Experimental design	Plot design	Random complete blocks (2 trials)
	Plot size	70 m ² (2 trials)
	Number of rep.	4 replications (2 trials)
Crop n°1	Trials per crop	Sugar beet - BEAVA (2 trials)
	Varieties per crop	Tisserin (2 trials)
	Sowing period	15/04 or 29/04
Replacement crops	Trials per crop	Garden pea - PIBSX (2 trials) Common sunflower - HELAN (2 trials) Maize - ZEAMX (2 trials) Potato - SOLTU (2 trials)
	Varieties per crop	PIBST: Safran (2 trials) HELAN: Isidor (2 trials) ZEAMX: Falkone (2 trials) SOLTU: Bintje (2 trials)
	Sowing period	PIBST, HELAN, ZEAMX, SOLTU: 31/05/2019
	Soil preparation	Before sowing succeeding crops, 2 soil preparations were made: - a superficial soil preparation (harrow) - a deep soil preparation (ploughing).
Application	Number of appl.	1 (2 trials)
	Crop stage at appl.	BEAVA: BBCH 14
	Timing of application	Post-emergence of the crop n°1. 14 and 3 days before sowing replacement crops
	Spray volumes	150 L/ha (2 trials)
Assessment	Assessment types	- Crop emergence : % of emergence and delay of emergence - Phytotoxicity as % of total leaf area affected by symptom where 0% = no phytotoxicity symptom and 100% = crop destroyed - Crop vigour on a 0-10 (or 0-5) linear scale, where 0 = no crop and 10 = the most vigorous plot within the trial area
	Statistical analysis	Data were then analysed using a two-way ANOVA on untransformed or transformed data. The probability of non-significant differences occurring between treatment means is calculated as the F probability value p(F). Student-Newman-Keuls multiple comparison test was applied to separate any significant treatment differences that may be implied by the ANOVA and these are indicated by a letter: treatment means with at least one letter in common are not significantly different according to the test initiated at the 95% confidence level.
	Assessment dates	Phytotoxicity was checked at: - 1 and 2 weeks after the first emergence in the untreated - at stage BBCH 14 to 16 of the crop - at stage 10-12 leaves or at crop cover complete (BBCH 39) - at flowering
Other information	Field / greenhouse	Field (2 trials)
	Weeds	Weed free conditions (2 trials)

Standard methods

The following EPPO guidelines and CEB methods were followed:

PP 1/135(4)	Phytotoxicity assessment
PP 1/152(4)	Design and analysis of efficacy evaluation trials
PP 1/181(4)	Conduct and reporting of efficacy evaluation trials including GEP
PP 1/207(2)	Effects on succeeding crops
CEB 96	Effets sur culture d'herbicide appliqué sur culture précédente (<i>Effects on crop of an herbicide applied on a previous crop</i>)

Treatments

All treatments were applied on sugar beets as foliar spray with a plot sprayer at recommended spray volume. AG-E1-500 SC1 was applied once at N rate (2 L/ha) and at 2N rate (4 L/ha). No standard was applied. The applications were made post-emergence of the crop, at BBCH 14 (4 leaves unfolded). Details of the treatments are given in the following table.

Table 3.5-3: Treatments applied in the replacement crop trials - field

Treatment	Active substances	Product name	Application rate	Application timing
Test product - N rate	ethofumesate 500 g/L	AG-E1-500 SC1	2 L/ha	BBCH 14
Test product - 2N rate	ethofumesate 500 g/L	AG-E1-500 SC1	4 L/ha	BBCH 14

Implantation of succeeding crops

Sugar beets were destroyed a few days after the application.

Before implantation of replacement crops, 2 kinds of soil preparation were made:

- a superficial soil preparation (harrow),
- a deep soil preparation (ploughing).

For each replacement crop, tillage made between sugar beet destruction and replacement crop implantation was made in a same single direction for every tillage tool on each crop to minimize soil displacement and to make it homogeneous. The drilling was realised perpendicular to the direction of the application.

In trial FR19HUBEAVA101A, the replacement crops were implemented 14 days after application.

In trial FR19HUBEAVA101B, the replacement crops were implemented 3 days after application.

Results are summarized in the following tables.

[illegible][illegible]

Results of 2 succeeding crop trials carried out in 2019 showed that garden pea (PIBSX), sunflower (HELAN) and maize (ZEAMX) can be used as replacement crops in case of failure of the beets crops treated with AG-E1-500 SC1.

On potato (SOLTU) the tested N rate (total 2 L/ha) induced acceptable phytotoxicity (<15%) with superficial preparation of the soil and slight phytotoxicity (<10%) with ploughing.

Laboratory study:

Hereafter is presented the assessment of the possible effect of AG-E1-500 SC1 on crops grown as rotational or replacement crops after a crop treated with AG-E1-500 SC1. This assessment is conducted in accordance with the EPPO Standard PP 1/207 (2) *Effects on succeeding crops*.

A laboratory study was conducted to determine the phytotoxic effects of the herbicide product ETHOSAT 500 (a.s. 500 g/L ethofumesate) on succeeding crops. This study No. PL0102 was conducted in Germany in 2004 by LK Westfalen-Lippe, Ref. Landbau und Pflanzenschutz Münster.

This study was not conducted under the Principles of Good Laboratory Practice (GLP) but was conducted with reference to the further GLP requirements and in accordance with the Principles of Good Experimental Practice (GEP) as outlined in the German plant protection law. The bioassay was conducted with regards to the following guidelines:

- HEIDLER G et al, 1993: *Prüfung der Phytotoxizität von Herbiziden auf nachgebaute Kulturen*
- PESTEMER, W P. PUCELİK-GÜNTHER, 1997: *Standardized Bioassay for the Determination of ED₁₀ -(NOEL) and ED₅₀ values for herbicides and selected following crops in soil.*

Procedure

A total of 6 plant species were chosen for the test: spring barley (*Hordeum distichon*), winter rape (*Brassica spp napus*), carnation clover (*Trifolium incarnatum*), pea (*Pisum sativum*), sugar beet (*Beta vulgaris*) and perennial ryegrass (*Lolium perenne*).

The product was applied on the experimental field of the testing facility (Loamy Sand soil type) and 400 g of soil substrate (treated or untreated) was put in flowerpots. The seeds of each crop species were sown on the top and then covered with additional 60 g of soil substrate. There were 6 replicates for each crop species.

The sensitivity of the various crops to the product was measured using the NOEL (no-observable effect level) that can be read from the dose-response curve as the concentration which causes a reduction of 10% compared to the untreated control (NOEL: EC₁₀). Thus the EC₁₀ value marks the effective dose which causes only a reduction in weight of 10%.

The following concentrations of the herbicidal product were tested:

Concentration in the soil	Corresponding application rate*
20 µL/kg of soil	10N rate
2.0 µL/kg of soil	N rate
0.2 µL/kg of soil	0.1N rate
0.02 µL/kg of soil	0.01N rate
0.002 µL/kg of soil	0.001N rate

* N = 2 L/ha

The complete material and methods (soil, crop varieties, application technique, etc.) is described in the study report.

The pots were kept in a climatic chamber and the phytotoxicity symptoms were regularly checked. At the end of the experimental phase all plants were cut off directly above the soil and weighted to determine the fresh weights. Results of the phytotoxicity symptoms and the fresh weight are given hereafter.

Table 3.5-6: Mean fresh weight of the plants in relation to the concentration of ETHOSAT 500 (500 g/L ethofumesate) - The fresh weight is given in percentage (untreated control = 100%)

Plant species	Concentration of the test substance ETHOSAT 500				
	0.002 µL/kg	0.02 µL/kg	0.2 µL/kg	2.0 µL/kg	20 µL/kg
Spring barley <i>Hordeum distichon</i>	96	103	100	4	0
Winter rape <i>Brassica napus</i>	102	79	107	70	94
Carnation clover <i>Trifolium incarnatum</i>	49	105	59	43	0
Pea <i>Pisum sativum</i>	75	84	81	76	13
Sugar beet <i>Beta vulgaris</i>	59	77	82	69	54
Perennial ryegrass <i>Lolium perenne</i>	87	93	103	74	11

The results regarding the mean fresh weight of the various crop species allowed to determine the relative EC₁₀ values (see next Table 3.5-7, left column) for spring barley, carnation clover and perennial ryegrass. For pea and sugar beet, the EC₁₀ value could not be determined but it must be a concentration lower than 0.002 µL/kg. For winter rape the EC₁₀ value could not be determined but it must be a concentration higher than 20 µL/kg.

Table 3.5-7: EC₁₀ values and EC₅₀ values determined for ETHOSAT 500 (500 g/L ethofumesate) in soil and selected succeeding crops

Plant species	EC ₁₀ value determined in relation to the tested concentrations (µL/kg)	NOEL (EC ₁₀ value) derived from the dose-response curve (µL/kg)	EC ₅₀ value derived from the dose-response curve (µL/kg)
Spring barley <i>Hordeum distichon</i>	0.2 µL/kg < EC ₁₀ < 2.00 µL/kg	EC ₁₀ = 0.250 µL/kg	EC ₅₀ = 0.650 µL/kg
Winter rape <i>Brassica napus</i>	20.0 µL/kg < EC ₁₀	EC ₁₀ = n.d*	20 µL/kg < EC ₅₀
Carnation clover <i>Trifolium incarnatum</i>	0.02 µL/kg < EC ₁₀ < 0.2 µL/kg	EC ₁₀ = 0.042 µL/kg	EC ₅₀ = 0.600 µL/kg
Pea <i>Pisum sativum</i>	EC ₁₀ < 0.002 µL/kg	EC ₁₀ = n.d* 2 µL/kg **	EC ₅₀ = 5.0 µL/kg
Sugar beet <i>Beta vulgaris</i>	EC ₁₀ < 0.002 µL/kg	EC ₁₀ = n.d* 2 µL/kg **	20 µL/kg < EC ₅₀
Perennial ryegrass <i>Lolium perenne</i>	0.2 µL/kg < EC ₁₀ < 2.00 µL/kg	EC ₁₀ = 0.520 µL/kg	EC ₅₀ = 4.6 µL/kg

*n.d.: not determinable.

** on pea & sugar beet, study No.PL0102, the values are based on comments in the discussion of the report (page 16).

Predicted Environmental Concentration of the product in soil (PECsoil)

The rate of 2 L/ha of AG-E1-500 SC1 was taken into account for calculations as this is the maximum intended rate for this submission, so it is a worst-case.

Initial PECsoil value was calculated according to the formula given by Kloskowski *et al.* (1999) according to EPPO Standard PP 1/207 (2) *Effects on succeeding crops*.

PEC_{initial}

$$PEC_{ini} = \frac{A \cdot (1 - f_{int})}{100 \cdot d \cdot bd}$$

where

A = application rate [g/ha]
 f_{int} = fraction intercepted by plant cover
 d = depth of the soil layer [cm]
 bd = bulk soil density [g/cm³]

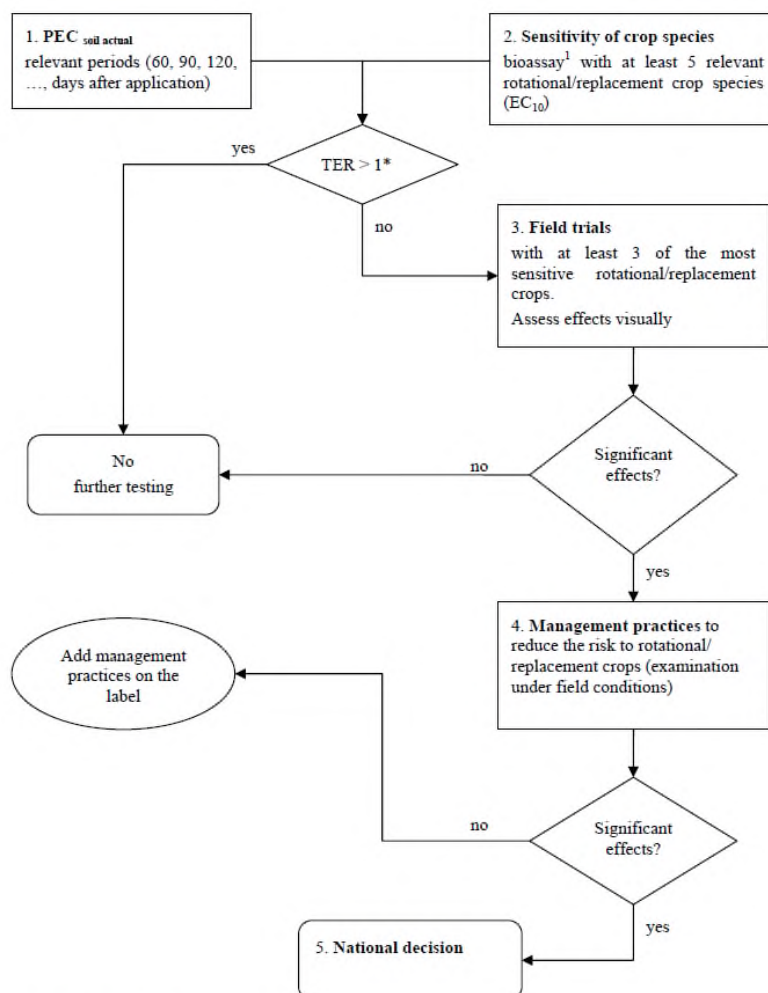
A = 2000 mL f.p./ha
 f_{int} = 0.20 (products applied from BBCH 10 to 19, on sugar beets) - EPPO PP 1/207 (2)
 d = 5 cm (2.5 to 5 cm according to EPPO Standard PP 1/207 (2)) or 20 cm for ploughing
 bd = 1.5 g/cm³ (according to EPPO Standard PP 1/207 (2))

For AG-E1-500 SC1 at 2 L/ha:

- following minimum cultivation to 5 cm: $PEC_{initial} = [2000 \cdot (1 - 0.20)] / [100 \cdot 5 \cdot 1.5] = 2.133 \mu\text{L f.p./kg soil}$
- following ploughing to 20 cm: $PEC_{initial} = [2000 \cdot (1 - 0.20)] / [100 \cdot 20 \cdot 1.5] = 0.533 \mu\text{L f.p./kg soil}$

Risk assessment

Risk to succeeding crops was assessed using the TER approach. TER were calculated by comparison of the toxicity (EC_{10}) to exposure (PEC_{soil}) and then compared with the trigger value of 1.



* or the specific national level, if higher

Decision-support scheme on the extent of testing needed to examine effects on succeeding crops and on the consequent recommendations

TER are calculated first with the $PEC_{initial}$. If TER is lower than 1, damage to relevant succeeding crop is possible then the TER is recalculated using PEC_{actual} at 7 days after application. If TER at 7 days is still

lower than 1, the TER is recalculated using PEC_{actual} at 14 days after application, then at 30 days after application, etc.

The calculations are stopped when TER value is higher than 1.

Results

The EC_{10} values and PEC initial values for AG-E1-500 SC1 after application (0 day) are presented in Table 3.5-8 below. The EC_{10} values are reported from the study No.PL0102.

Table 3.5-8: AG-E1-500 SC1 - PEC -values and TER-calculation based on EC_{10} -values from study No. PL0102 - 0 day after application

Succeeding / replacement crop			Days after application	EC_{10} of succeeding crops	$PEC_{initial}$ (soil depth 5 cm)	$PEC_{initial}$ (soil depth 20 cm)
Common name	Scientific name	EPPO Code		$\mu\text{L f.p./kg dry soil}$	$\mu\text{L f.p./kg soil 5 cm}$	$\mu\text{L f.p./kg soil 20 cm}$
Spring barley	<i>Hordeum distichon</i>	HORDI	0 (initial)	0.250	2.133	0.533
Winter rape	<i>Brassica napus</i>	BRSNN	0 (initial)	> 20.0	2.133	0.533
Carnation clover	<i>Trifolium incarnatum</i>	TRFIN	0 (initial)	0.042	2.133	0.533
Pea	<i>Pisum sativum</i>	PIBSX	0 (initial)	2*	2.133	0.533
Sugar beet	<i>Beta vulgaris</i>	BEAVX	0 (initial)	2*	2.133	0.533
Perennial ryegrass	<i>Lolium perenne</i>	LOLPE	0 (initial)	0.520	2.133	0.533

* On pea & sugar beet, study No.PL0102 the values are based on comments in the discussion of the report (page 16).

A combined laboratory and field kinetic soil DT_{50} for modelling of the active substance ethofumesate is provided in the EFSA conclusion, EFSA 2016; 14(1):4374. A geomean value of 26.2 days was calculated with normalisation to 10 kPa or pF2, 20°C with Q10 of 2.58 and Walker equation coefficient 0.7.

This value of 26.2 days will be taken into account as DT_{50soil} .

Actual PEC_{soil} value is calculated according to the formula given by Kloskowski *et al.* (1999) according to EPPO Standard PP 1/207 (2).

PEC_{actual}

$$PEC_{act}(t) = PEC_{ini} \cdot e^{-kt} = PEC_{ini} \cdot e^{-\frac{t \ln 2}{DT_{50}}}$$

$PEC_{ini} = 2.133 \mu\text{L f.p./kg soil}$ or $0.533 \mu\text{L f.p./kg soil}$

t = days after application

$DT_{50} = 26.2$ days

The following table presents the results of the TER calculations for AG-E1-500 SC1 following minimum cultivation to 5 cm and ploughing to 20 cm. The smallest interval after application permitting a TER value higher than 1 is presented for each cultivation type. TER values above 1 are highlighted.

Table 3.5-9: AG-E1-500 SC1 - PEC -values and TER-calculation based on EC_{10} -values from study No. PL0102

Succeeding / replacement crop			Days after application	EC_{10}	PEC_{actual}	PEC_{actual}	TER	TER
Common name	Scientific name	EPPO Code		$\mu\text{L f.p./kg dry soil}$	$\mu\text{L f.p./kg dry soil 5 cm}$	$\mu\text{L f.p./kg dry soil 20 cm}$	EC_{10}/PEC 5 cm	EC_{10}/PEC 20 cm
Spring barley	<i>Hordeum distichon</i>	HORDI	30 days	0.250	0.964	0.241	0.26	1.04
			90 days	0.250	0.197	0.049	1.27	5.10

Succeeding / replacement crop			Days after application	EC ₁₀	PEC _{actual}	PEC _{actual}	TER	TER
Common name	Scientific name	EPPO Code		µL f.p./kg dry soil	µL f.p./kg dry soil 5 cm	µL f.p./kg dry soil 20 cm	EC ₁₀ /PEC 5 cm	EC ₁₀ /PEC 20 cm
Winter rape	<i>Brassica napus</i>	BRSNN	0 (initial)	> 20.0	2.133	0.533	> 9.38	> 37.5
Pea	<i>Pisum sativum</i>	PIBSX	0 (initial)	2	2.133	0.533	0.94	3.75
			5 days	2	1.869	0.467	1.07	4.28
Sugar beet	<i>Beta vulgaris</i>	BEAVX	0 (initial)	2	2.133	0.533	0.94	3.75
			5 days	2	1.869	0.467	1.07	4.28
Carnation clover	<i>Trifolium incarnatum</i>	TRFIN	105 days	0.042	0.133	0.033	0.32	1.27
			150 days	0.042	0.040	0.010	1.05	4.20
Perennial ryegrass	<i>Lolium perenne</i>	LOLPE	0 days	0.520	2.133	0.533	0.24	0.98
			60 days	0.520	0.436	0.109	1.19	4.77

Conclusions:

A laboratory study (No.PL0102) was carried out to determine the EC₁₀ in soil for ETHOSAT 500 (a.s. 500 g/L ethofumesate) on 5 representative plant species.

These results are extrapolated to AG-E1-500 SC1 as it contains 500 g/L ethofumesate.

The calculations done according to the methodology described in EPPO Standard PP 1/207 (2) *Effects on succeeding crops* permitted to conclude that:

* following minimum cultivation to 5 cm:

- spring barley can be safely sown at least 90 days (3 months) after application,
- winter rape can be safely sown directly after application,
- pea can be safely sown at least 5 days after application,
- sugar beet can be safely sown at least 5 days after application,
- carnation clover can be safely sown at least 150 days (5 months) after application,
- perennial ryegrass can be safely sown at least 60 days (2 months) after application.

* following ploughing to 20 cm:

- spring barley can be safely sown at least 30 days (1 month) after application,
- winter rape can be safely sown directly after application,
- pea can be safely sown directly after application,
- sugar beet can be safely sown directly after application,
- carnation clover can be safely sown at least 105 days (3.5 months) after application,
- perennial ryegrass can be safely sown directly after application.

Conclusion on succeeding / replacement crops

Ethofumesate is a well know active which has been used for many years without any issues on succeeding crops. Therefore, the label for this project should contain the crop information that are presented in the next table 3.5-10.

A total of 2 field trials on replacement crops and 1 study in laboratory evaluated the impact of AG-E1-500 SC1 on succeeding / replacement crops.

The following table summarises the findings.

Table 3.5-10: AG-E1-500 SC1 - Findings on succeeding / replacement crops

Succeeding / replacement crop			Findings	Source
Common name	Scientific name	EPPO Code		
Pea	<i>Pisum sativum</i>	PIBSX	Can be safely sown at least 3 days after application, with harrow or ploughing	Trials FR19HUBEAVA101A and FR19HUBEAVA101B
Sunflower	<i>Helianthus annuus</i>	HELAN	Can be safely sown at least 3 days after application, with harrow or ploughing	Trials FR19HUBEAVA101A and FR19HUBEAVA101B
Maize	<i>Zea mays</i>	ZEAMX	Can be safely sown at least 3 days after application, with harrow or ploughing	Trials FR19HUBEAVA101A and FR19HUBEAVA101B
Potato	<i>Solanum tuberosum</i>	SOLTU	Can be safely sown at least 3 days after application, with ploughing	Trials FR19HUBEAVA101A and FR19HUBEAVA101B
Spring barley	<i>Hordeum distichon</i>	HORDI	Can be safely sown at least 90 days (3 months) after application following minimum cultivation to 5 cm Can be safely sown at least 30 days (1 month) after application following ploughing to 20 cm	Study No. PL0102 + EPPO PP1/207 calculations
Winter rape	<i>Brassica napus</i>	BRSNN	Can be safely sown directly after application following minimum cultivation to 5 cm or ploughing to 20 cm	Study No. PL0102 + EPPO PP1/207 calculations
Sugar beet	<i>Beta vulgaris</i>	BEAVX	Can be safely sown at least 5 days after application following minimum cultivation to 5 cm Can be safely sown directly after application following ploughing to 20 cm	Study No. PL0102 + EPPO PP1/207 calculations
Carnation clover	<i>Trifolium incarnatum</i>	TRFIN	Can be safely sown at least 150 days (5 months) after application following minimum cultivation to 5 cm Can be safely sown at least 105 days (3.5 months) after application following ploughing to 20 cm	Study No. PL0102 + EPPO PP1/207 calculations
Perennial ryegrass	<i>Lolium perenne</i>	LOLPE	Can be safely sown at least 60 days (2 months) after application following minimum cultivation to 5 cm Can be safely sown directly after application following ploughing to 20 cm	Study No. PL0102 + EPPO PP1/207 calculations

Comments of zRMS:

Two field trials carried out in the Maritime part of France in 2019 (FR19HUBEAVA101A and FR19HUBEAVA101B, KCP 6.5 48 and 49) tested phytotoxicity of AG-E1-500 SC1 to the possible replacement crops, using garden pea, sunflower, maize and potato, and applying two types of soil preparation before drilling: superficial harrowing or deep ploughing. In one of the trials the crops replaced sugar beet 14 days after application of AG-E1-500 SC1 on it, while in the other trial – 3 days after that application.

The laboratory study PL0102 (KCP 6.5 50), carried out in 2004 in Münster, Germany, by LK Westfalen-Lippe, Ref. Landbau und Pflanzenschutz, determined EC₁₀ of ethofumesate for six plant species: spring barley, winter rape, carnation clover, pea, sugar beet and perennial ryegrass. Initial and actual PEC_{soil} values for ethofumesate have been calculated by the applicant according to the EPPO Standard PP 1/207 (2) *Effects on succeeding crops*, based on the target 1N dose rate of AG-E1-500 SC1, and using DT_{50soil} value provided by EFSA conclusion (2016), quoted by the applicant within the chapter. EC₁₀ and PEC values were used in calculation of TER values for the six tested plant species.

The French trials were carried out by GEP-certified unit. The PL0102 trial (KCP 6.5 50) was conducted according to contemporary (2004) requirements of German plant protection law, and following two acknowledged guidelines which are quoted by the applicant. To the opinion of zRMS, although fairly old, this laboratory study is also reliable and provides valid input to the complex TER calculation carried out presently and based, on the other hand, on more recent EFSA conclusion (2016).

The applicant's conclusions concerning all crops tested in the field and the laboratory trials, presented in the Table 3.5-10 above, can be used to produce label recommendations concerning succeeding / replacement crops. Nevertheless, the label proposed by the applicant in Poland recommends growing crops other than sugar beet only after harvesting, at a standard time, of the crop in which the AG-E1-500 SC1 has been applied. In case of early crop termination the only replacement crop allowed is sugar beet, provided that no ethofumesate containing product is applied in that same growth season and that the dose rate of 1 kg a.s. /ha will not be exceeded in 3 years.

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

AG-E1-500 SC1 was formerly approved on sugar beet in several countries of Europe but is currently not approved anymore. During this period of approval, no particular problems related to adjacent crops were reported to Adama. Nevertheless, as an herbicide, AG-E1-500 SC1 may cause damage to adjacent crops if not applied properly and in the suitable climatic conditions.

Comments of zRMS:

In December 2021, 12 products containing ethofumesate were authorized in Poland. In many other MSs the products containing this active are currently or had been previously authorized. Although no data on the effect on adjacent crops have been submitted in the present dossier, the zRMS considers this acceptable, because ethofumesate is not an active unknown to the users.

Polish label already contains standard recommendation “*During the application do not allow spray drift to the adjacent crops*”. The zRMS recommends issuing warning to the same meaning by the cMSs Hungary and Slovakia.

Calculation for estimating residues within PAE based on ISO 16119

This calculation was made according to EPPO PP 1/292.

Up to 2.6% of the spray solution will remain in the PAE following application (according to ISO 16119). Assuming a dose of 0.66 L/ha and a product containing 500 g/L of active substance (a.s.) the following would therefore apply:

Amount of a.s. in 1000 L sprayer (assuming 100 L/ha water)	$1000/100 = 10 \times 0.66 \text{ L/ha} = 6.6 \text{ L/ha}$ applied at $500 \text{ g a.s./L} = 3\,300 \text{ g a.s./ha}$	3 300 g a.s.
Amount left after spraying (2.6%)	$3\,300 \times 2.6\%$	85.8 g a.s.
Amount left after 1st stage of washout procedure (2.6%)	$85.8 \times 2.6\%$	2.2308 g a.s.
Amount left after 2nd stage of washout procedure (2.6%)	$2.2308 \times 2.6\%$	0.0580008 g a.s.
Amount after re-filling sprayer (1000 L)	-	0.0580008 g a.s.
Dose applied (at 400 L/ha) to 2.5 ha	$0.0580008 / 2.5$	0.02320032 g a.s./ha

In the table above, the maximum dose liable to be applied following a two-stage cleaning procedure is 0.02320032 g a.s./ha. This dose is then used to calculate the toxicity:exposure ratio.

Data on the biological activity of AG-E1-500 SC1 are available from the two standard test models "seedling emergence" (KCP 10.6.2/01) and "vegetative vigour" (KCP 10.6.2/02), which are considered to be most relevant for the assessment of effects on non-target plants (including non-target crops) after broadcast spraying of AG-E1-500 SC1 and tank residues, respectively. The tests were performed according to OECD 208 (2006) and OECD 227 (2006), respectively, and the test substance AG-E1-500 SC1 was sprayed to the test plants or to the soil after sowing of plants. Each test was performed in 10 representative plant species.

The acceptability of the predicted residue level of AG-E1-500 SC1 was assessed by a comparison of the exposure concentration predicted for the re-use of the application equipment with the effect rates (ER₅₀) in the most sensitive plant species of the “vegetative vigour” and “seedling emergence” test. Effect on plant weight was considered as reliable endpoint for toxic effects and the most sensitive of these toxicity figures was used for the following risk assessment:

Maximum predicted exposure of non-target crops with spray residues:

PER = is 0.02320032 g a.s./ha

Risk from spray residues for seedling emergence of non-target plants:

Toxicity endpoints obtained from reference:

KCP 10.6.2/01: Duffner, A., (2020a): Effects on the Seedling Emergence and Seedling Growth on Non-Target Terrestrial Plant Species under Greenhouse Conditions.

Lowest ER ₅₀	0.098 L prod./ha (<i>Triticum aestivum</i>), corresponding to 49 g a.s./ha
Lowest NOER	0.020 L prod./ha (<i>Triticum aestivum</i>), corresponding to 10 g a.s./ha
TER (ER ₅₀ /PER)	2112
NOER/PER	431

Risk from spray residues for vegetative vigour of non-target plants:

Toxicity endpoints obtained from reference:

KCP 10.6.2/02: Duffner, A., (2020b): Effects on the Vegetative Vigour of Non-Target Terrestrial Plant Species under Greenhouse Conditions.

Lowest ER ₅₀	0.37 L prod./ha (<i>Medicago sativa</i>), corresponding to 185 g a.s./ha
Lowest NOER	<0.027 L prod./ha (<i>Medicago sativa</i> , <i>Lepidum sativum</i>), corresponding to 13.5 g a.s./ha
TER (ER ₅₀ /PER)	7974
NOER/PER	582

The assessment is based on worst-case median effective rates and Toxicity/Exposure Ratios are compared to the standard trigger of 5 for acceptability of risk for terrestrial non-target plants as in accordance with the guidance document SANCO/10329/2002 rev.2 final (October 17, 2002)^[1]. The ER₅₀ based TER values for the most sensitive plant species of both plant toxicity tests are greater than 5^[2] by more than 2 orders of magnitude. Therefore, the potential risk for non-target terrestrial plants from product residues remaining in tanks following cleaning is considered to be acceptable.

Conclusion: The effectiveness of standard cleaning procedures according to Good Agriculture Practice was assessed for the product AG-E1-500 SC1 on a theoretical basis. Residues of the plant protection product remaining in the tank after two washouts with water and the predicted exposure of non-target crops after re-use of the application equipment were calculated for worst case conditions. Compared to the effect levels for non-target plants, which are most likely to be affected by herbicide residues, residue levels are far below concentrations that might pose a risk for the terrestrial flora including non-target crops. Thus, any detrimental effect on plants from tank residues can widely be excluded. The cleaning method is therefore considered to be acceptable, and the performance of any small-scale or a large-scale test is not considered to be required.

Comments of zRMS:

The applicant's reasoning and calculation is complete and the issue of residue in the sprayer tank has been addressed adequately. No testing of tank cleaning procedure is necessary.

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

No adverse effect of AG-E1-500 SC1 on beneficial and other non-target organisms was reported in the efficacy and selectivity trials presented in this dossier.

3.6 Other/special studies

^[1] Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC

^[2] A trigger of 5 can be applied, if at least 6 plant species have been tested

None.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Testing facility	Full address	GEP certified	Certibase link	Valid from - to
Agreco Sp. z.o.o	al, Lipowa 21, lok, 1, 53-124 Wrocław - POLAND	Y	1d68e3a4415	16-Apr-2018 15-Apr-2023
Agro Research Consulting (ARC)	ul. Nadburzańska 32, 99-400 Łowicz, - POLAND	Y	1d68e3a427c	6-Mar-2018 5-Mar-2023
BioChem agrar	Kupferstr.6, D-04827 Machern OT Gerichshain - GERMANY	Y	1d68e3a408b	24-Mar-2014 24-Mar-2019
			1d68e3a4312	21-Mar-2019 21-Mar-2024
Czech University of Life Sciences (Ceska zemedelska univerzita v Praze)	Kamýcká 129, 165 00 Prague Suchdol - CZECH REPUBLIC	Y	1d68ee9bbfb	20-Jun-2016 31-Dec-2021
Ephydia	1 rue de Courcellette 62450 Martinpuich FRANCE	Y	-	-
Fertico Sp. z.o.o	Goliany 43, 05-620 Bledow - POLAND	Y	1d68e3a43e1	26-Apr-2011 31-Dec-2019
Fyse, Ltd., Dep. AgroLab	Skolska 88, 991 09 Kolare - SLOVAKIA	Y	1d68e3a413d	4-Feb-2016 4-Feb-2021
GemerproduktValice OVD	Okružna 3771, 979 01 Rimavska Sobota - SLOVAKIA	Y	1d68e3a414d	12-Apr-2016 12-Apr-2021
Hetterich Fieldwork GbR	Bamberger Str, 50 , 97359 Schwarzach - GERMANY	Y	1d68e3a3ffe	20-Jun-2014 20-Jun-2019
			1d68e3a43dc	20-Jun-2019 19-Jun-2024
Növénypathyka Kft.	Damjanich u.47, H-7400 Kaposvar - HUNGARY	Y	1d68e3a4055	22-Oct-2014 31-Oct-2019
Poznań University of Life Sciences	Ul. Mazowiecka 45/46, 60-623 Poznan - POLAND	Y	1d68e3a3ce8	14-Oct-2010 31-Dec-2019
Staphyt Sp. z.o.o	ul, Ziebicka 2, 60-164 Poznan - POLAND	Y	1d68e3a43e0	1-Jan-2012 31-Dec-2019
SynTech Research Hungary Kft.	Török Ignac u.30, H-9700 Szombathely - HUNGARY	Y	1d68e3a4363	14-Aug-2016 15-Aug-2021
Trialtec GmbH	Kampenredder 5, 24363 Haby - GERMANY	Y	1d68e3a43ab	22-Apr-2018 23-Apr-2023
Ustredny kontrolny a skusobny ustav polnohospodarsky	Matuskova 21, 833 16 Bratislava - SLOVAKIA	Y	1d68e3a416e	14-Feb-2016 15-Feb-2021
Zkusebni stanice (ZS) Nechanice s.r.o.	Štolbova 319, 503 15 Nechanice – CZECH REPUBLIC	Y	1d68ee9bb69	1-Sep-2016 31-Aug-2021

GEP certificates that are not available on Certibase are provided hereafter.

GEP certificate of Ephydia

Appendix 4). GEP Certificate



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

DÉCISION D'AGRÈMENT POUR RÉALISER DES ESSAIS OFFICIELLEMENT RECONNUS

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 2859,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 13/10/2017,

L'agrément pour réaliser des essais officiellement reconnus est renouvelé, à l'organisme :

EPHYDIA
1 rue de courcelette
62450 MARTINPUICH

sous le numéro : **BPE - 035**

POUR LE PERIMETRE SUIVANT :

UNITE(S)	SECTEUR(S) D'ACTIVITE
EPHYDIA 48 bis grand tue 62450 Martinpuich (<i>unité centrale</i>)	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
unité d'expérimentation morisel route d'ailly sur noye 80110 Morisel	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum

Cet agrément est délivré pour une durée de cinq ans à compter du **30/01/2018** jusqu'au **29/01/2023**. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du **30/01/2018**.

Date : 08 JAN 2018

Le Chef du Service des Actions Sanitaires
en Production Primaire

Appendix 1 Lists of data considered in support of the evaluation

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 6 /01	Wasmer, L.	2021	BAD of AG-E1-500 SC1 in the Central Registration zone (North-East and South-East EPPO climatic zones) Unpublished	N	Y	New data	ADAMA Agan Ltd.
KCP 6.2 /01 Also cited in KCP 6.4	KUKULA A.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in Poland in 2019 AGRECO Sp. z.o.o. Report n°: PL19HEBEAVA067A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /02 Also cited in KCP 6.4	KUKULA A.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in Poland in 2019 AGRECO Sp. z.o.o. Report n°: PL19HEBEAVA067B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /03 Also cited in KCP 6.4	KUKULA A.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in Poland in 2019 AGRECO Sp. z.o.o. Report n°: PL19HEBEAVA067C GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /04 Also cited in KCP 6.4	KUKULA A.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in Poland in 2019 AGRECO Sp. z.o.o. Report n°: PL19HEBEAVA067D GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /05 Also cited in KCP 6.4	SZEMENDERA A.	2019	Efficacy of AG-E1-500 SC1 in control of weeds in sugarbeet, Poland 2019 FERTICO Sp. z.o.o. Report n°: PL19HEBEAVA067G GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /06 Also cited in KCP 6.4	SZEMENDERA A.	2019	Efficacy of AG-E1-500 SC1 in control of weeds in sugarbeet, Poland 2019 FERTICO Sp. z.o.o. Report n°: PL19HEBEAVA067H GEP	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 6.2 /07 Also cited in KCP 6.4	SZEMENDERA A.	2020	Unpublished Efficacy of AG-E1-500 SC1 in control of weeds in sugar beet, Poland 2020 FERTICO Sp. z.o.o. Report n°: PL20HEBEAVA059A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /08 Also cited in KCP 6.4	GAJEK D.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in POLAND in 2020 Agro Research Consulting (ARC) Report n°: PL20HEBEAVA059B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /09 Also cited in KCP 6.4	PAWLAK A.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in Poland in 2020 STAPHYT Sp. z.o.o Report n°: PL20HEBEAVA059C GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /10 Also cited in KCP 6.4	PAWLAK A.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in Poland in 2020 STAPHYT Sp. z.o.o Report n°: PL20HEBEAVA059H GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /11 Also cited in KCP 6.4	RITECZ J.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Hungary in 2019 SynTech Research Hungary Kft. Report n°: HU19HEBEAVA100A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /12 Also cited in KCP 6.4	HODI L.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Hungary in 2019 SynTech Research Hungary Kft. Report n°: HU19HEBEAVA100B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 6.2 /13 Also cited in KCP 6.4	HOFFMANNE PATHY Z.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Hungary in 2019. Növénypathyka Kft. Report n°: HU19HEBEAVA100C GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /14 Also cited in KCP 6.4	HOFFMANNE PATHY Z.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Hungary in 2019. Növénypathyka Kft. Report n°: HU19HEBEAVA100D GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /15 Also cited in KCP 6.4	LABANT A.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Hungary in 2020 Növénypathyka Kft. Report n°: HU20HEBEAVA101A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /16 Also cited in KCP 6.4	LABANT A.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Hungary in 2020 Növénypathyka Kft. Report n°: HU20HEBEAVA101B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /17 Also cited in KCP 6.4	ROCKAR M.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Slovakia in 2019 Fyse, Ltd., Dep. AgroLab Report n°: SK19HEBEAVA608A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /18 Also cited in KCP 6.4	BANICOVA J.	2019	Efficacy of AG-E1-500 SC1 (post-emergence; spring) against weeds in sugar beets in (Slovakia) in 2019 Fyse, Ltd., Dep. AgroLab Report n°: SK19HEBEAVA608B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /19	ROCKAR M.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Slovakia in 2020	N	Y	New study - Never submit-	ADAMA Agan Ltd.

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
Also cited in KCP 6.4			Fyse, Ltd., Dep. AgroLab Report n°: SK20HEBEAVA604A GEP Unpublished			ted before	
KCP 6.2 /20 Also cited in KCP 6.4	BANICOVA J.	2020	Efficacy of AG-E1-500 SC1 (post-emergence; spring) against weeds in sugar beets in (Slovakia) in 2020 Fyse, Ltd., Dep. AgroLab Report n°: SK20HEBEAVA604B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /21 Also cited in KCP 6.4	TÓTH F.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Slovakia in 2020 GEMERPRODUKT VALICE OVD Report n°: SK20HEBEAVA604C GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /22 Also cited in KCP 6.4	TÓTH F.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Slovakia in 2020 GEMERPRODUKT VALICE OVD Report n°: SK20HEBEAVA604D GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /23 Also cited in KCP 6.4	CERNY M.	2020	“Efficacy of AG-E1-500 SC1 in sugar beets after 2 way splitting post emergence application in Slovakia in 2020” Ustredny kontrolny a skusobny ustav polnohospodarsky Report n°: SK20HEBEAVA604E GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /24 Also cited in KCP 6.4	KOLAROVA M.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in the Czech Republic in 2019. Czech University of Life Sciences Report n°: CZ19HEBEAVA606A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /25 Also cited in	HORNIK P.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in the Czech Republic in 2019. ZS Nechanice	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 6.4			Report n°: CZ19HEBEAVA606B GEP Unpublished				
KCP 6.2 /26 Also cited in KCP 6.4	KOLAROVA M.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in the Czech Republic in 2020 Czech University of Life Sciences Report n°: CZ20HEBEAVA602A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /27 Also cited in KCP 6.4	HORNIK P.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in the Czech Republic in 2020 ZS Nechanice Report n°: CZ20HEBEAVA602B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /28 Also cited in KCP 6.4	ROHR J.	2020	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in Germany in 2020. Trialtec GmbH Report n°: DE20HEBEAVA602A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.2 /29 Also cited in KCP 6.4	ROHR J.	2019	Efficacy of AG-E1-500 SC1 in sugar beets after 3 way splitting post emergence application in Germany in 2020. Trialtec GmbH Report n°: DE20HEBEAVA602B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /30	SZEMENDERA A.	2019	Selectivity of AG-E1-500 SC1 in control of weeds in sugarbeet, Poland 2019 FERTICO Sp. z.o.o. Report n°: PL19HSBEAVA066A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /31	SZEMENDERA A.	2019	Selectivity of AG-E1-500 SC1 in control of weeds in sugarbeet, Poland 2019 FERTICO Sp. z.o.o. Report n°: PL19HSBEAVA066B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
KCP 6.4 /32	PAWLAK A.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 3* post-emergence application in Poland in 2019 STAPHYT Sp. z.o.o Report n°: PL19HSBEAVA066C GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /33	PAWLAK A.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 3* post-emergence application in Poland in 2019 STAPHYT Sp. z.o.o Report n°: PL19HSBEAVA066D GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /34	SZYMANSKA B.	2019	Determination of the selectivity of AG-E1-500 SC1 in cultivation sugar beet Poznań University of Life Sciences, Research and Education Center Gorzyń Report n°: PL19HSBEAVA066E GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /35	SZYMANSKA B.	2019	Determination of the selectivity of AG-E1-500 SC1 in cultivation sugar beet Poznań University of Life Sciences, Research and Education Center Gorzyń Report n°: PL19HSBEAVA066F GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /36	RITECZ J.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 2* post-emergence application in Hungary in 2019 SynTech Research Hungary Kft. Report n°: HU19HSBEAVA100A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /37	HODI L.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 2* post-emergence application in Hungary in 2019 SynTech Research Hungary Kft. Report n°: HU19HSBEAVA100B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /38	HOFFMANNE PATHY Z.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 2* post-emergence application in Hungary in 2019 Növénypatyika Kft.	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Report n°: HU19HSBEAVA100C GEP Unpublished				
KCP 6.4 /39	HOFFMANNE PATHY Z.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 2* post-emergence application in Hungary in 2019 Növénypathyka Kft. Report n°: HU19HSBEAVA100D GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /40	TOTH F.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 2* post-emergence application in Slovakia in 2019. GEMERPRODUKT VALICE OVD Report n°: SK19HSBEAVA604A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /41	TOTH F.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 2* post-emergence application in Slovakia in 2019. GEMERPRODUKT VALICE OVD Report n°: SK19HSBEAVA604B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /42	SOLTESZ J.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 2* post-emergence application in Slovakia in 2019 Fyse, Ltd., Dep. AgroLab Report n°: SK19HSBEAVA604C GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4 /43	BANICOVA J.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 2* post-emergence application in Slovakia in 2019 Fyse, Ltd., Dep. AgroLab Report n°: SK19HSBEAVA604D GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4/44	HETTERICH F.	2019	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 3* post-emergence application in Germany in 2019 Hetterich Fieldwork GbR Report n°: DE19HSBEAVA602A	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			GEP Unpublished				
KCP 6.4/45	ZICKART U.	2020	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 3* postemergence application, Germany 2020 BioChem agrar GmbH Report n°: DE20HSBEAVA600A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4/46	LAMERS K.	2020	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 3* postemergence application in Germany in 2020 BioChem agrar GmbH Report n°: DE20HSBEAVA605A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.4/47	LAMERS K.	2020	Determination of the selectivity of AG-E1-500 SC1 in sugar beet after 3* postemergence application in Germany in 2020 BioChem agrar GmbH Report n°: DE20HSBEAVA605B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.5/48	Barlet O.	2019	Selectivity of AG-E1-500 SC1 applied in post-emergence on several following crops (Potato, Maize, Sunflower and Pea) of sugar beet in France in 2019 SAS Ephydia ADAMA Agan Ltd., Report n°: FR19HUBEAVA101A GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.5/49	Barlet O.	2019	Selectivity of AG-E1-500 SC1 applied in post-emergence on several following crops (Potato, Maize, Sunflower and Pea) of sugar beet in France in 2019 SAS Ephydia ADAMA Agan Ltd., Report n°: FR19HUBEAVA101B GEP Unpublished	N	Y	New study - Never submit- ted before	ADAMA Agan Ltd.
KCP 6.5/50	KLENNER and WERSCHMANN	2004	Bioassay for the Determination of EC10-(NOEL-) Values of the Herbicide ETHOSAT 500 (a.i. 500 g/l Ethofumesate) in soil on Selected Succeeding Crops Landwirtschaftskammer Westfalen-lippe, Referat Landbau und Pflanzenschutz (RLP) Report n°: PL0102	N	N	-	ADAMA Agan Ltd.

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Vertebrate study Y/N	Data pro- tection claimed Y/N	Justification if data protec- tion is claimed	Owner
			Not GEP (Official organization) Unpublished				