

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

Product code: AG-F8-250 CS
Product name: RACER 250 CS
Chemical active substance:
Active substance: Flurochloridone 250 g/L

Central Zone
Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: ADAMA Polska
Submission date: January 2020
MS Finalisation date: October 2020 (initial Core Assessment)
March 2021 (final Core Assessment)

Version history

When	What
January 2020	dRR submitted by the Applicant
October 2020	<p>Initial zRMS assessment</p> <p>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.</p>
March 2021	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow.</p> <p>No comments after the commenting period.</p>

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

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

Comments of zRMS:

Conclusions from the evaluation were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are ~~visibly marked with the grey font~~.

No comments after the commenting period.

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

Abstract

Comments of zRMS:

The applicant has submitted 11 efficacy and 8 selectivity trials, aiming at the authorization of the herbicide product AG-F8-250 CS (Racer 250 CS), which contains 250 g/L of flurochloridone the active of the MoA group no. 12 (HRAC 2020). The applicant claims that AG-F8-250 CS (Racer 250 CS) is an improved version of another formulation, already registered in Poland under the trade name Racer 250 EC, and containing 250 g/L of flurochloridone as well. The former formulation is registered under the number R-8/2003 (14.05.2003). The authorization is sought in control of dicotyledonous weeds and *Echinochloa crus-galli* in potato crop, based on the art 33. of the EC regulation 1107/2009.

The recommended use of AG-F8-250CS (Racer 250 CS) is one of the range of uses of Racer 250 EC, therefore the former formulation is used in the presented efficacy dossier as the reference product.

Minimum Effective Dose

Dose rates of 1,0 and 1,5 L/ha representing respectively 50% and 75% of the target dose of AG-F8-250 CS were tested in all of the 11 efficacy trials. The dose response was more apparent between the 1,5 and 2,0 L/ha compared to 1,0 L/ha *versus* 1,5 L/ha. With two exceptions only, wherever the efficacy exceeded 95% it was achieved by the target dose rate alone. Therefore the dose rate 2,0 L/ha of AG-F8-250 CS has been considered as the proper minimum effective dose rate against majority of the weed species for which the label claim is made.

Efficacy tests

Based on the results of 11 efficacy trials carried out in Poland, the susceptibility of the following weed species was determined as follows:

Highly Susceptible	BRSNW, CAPBP, GASPA, MATIN, STEME, THLAR
Susceptible	CHEAL, GALAP, GERPU, POLCO, SOLNI,
Moderately susceptible	ECHCG, POLPE, VIOAR,

Resistance management. Although no resistance has been reported to date to flurochloridone *per se*, standard resistance management strategy must be incorporated in the product label, in order to constantly stimulate the end user's awareness of the resistance issue and of the risk involved. The applicant has proposed some resistance management strategies to be placed in the product label.

Phytotoxicity was monitored in 11 efficacy trials as symptoms on plants and was separately tested in 8 selectivity trials, of which six tested yield, five tested harvestable yield and three tested starch content in tubers. It has been concluded that no significant negative effect on yield and its parameters should be expected after application of the test item, compared to the former formulation used as standard reference.

No specific trials were conducted pertaining to effect on transformation process, impact on plants and plant parts used for propagation, impact on succeeding crops or on adjacent plants. As declared by the applicant, detailed information concerning these aspects had been submitted at first registration of flurochloridone product Racer 250 EC.

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

Table 011: Acceptability of intended uses (and respective risk-benefit ratio, if applicable)														
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g /as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Solanum tu- berosum/SOLTU-pre emergence	F	Dicotyledonous weed plants and <i>Echi- nochloa crus-galli</i>	Spraying	BBCH 00-09; BBCH 00-08; pre-emergence	a) 1 b) 1	n.a.	a) 2,0 l/ha b) 2,0 l/ha	a) 500 b) 500	100-400 200-250	n.a		A

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

** F: professional field use, Fn: non-professional field use, Fnp: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gnp: professional and non-professional greenhouse use, I: indoor application.

Column 15: zRMS conclusion.

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

3.2 Efficacy data (KCP 6)

Introduction

This document summaries efficacy data and information for plant protection product AG-F8-250 CS (Racer 250 CS) , capsule suspension, contain 250 g/L flurochloridone. The aim of the submission is authorisation of product AG-F8-250 CS (Racer 250 CS) contain 250 g/L of flurochloridone. AG-F8-250 CS (Racer 250 CS) stays formulation-improved version of already registered in Poland product Racer 250 EC. Racer 250 EC contain 250 g/L of flurochloridone , registered under number : R-8/2003 (14.-5.2003).

Recommended use of product AG-F8-250CS (Racer 250 CS) is included in range of use of Racer 250 EC , therefore Racer 250 EC is used in presented efficacy trials as reference product.

Description of active substances

Flurochloridone is approved under Regulation EC No 1107/2009 , inclusive Directive 2011/34/EU , inclusion date 01/06/2011, RMS Spain.

Mode of action

Flurochloridone is a selective herbicide belonging to the HRAC F1 group. It belongs to the pyrrolidone chemical group. This substance is not systemic since its migration in the plant is low. It inhibits the phytoene desaturase, PDS enzyme, and thus the synthesis of carotenoids which leads to the loss of the protective pigments of the chlorophyll molecules.

Flurochloridone penetrates in the plant by the underground plant parts between germination and seedling emergence.

Table 3.2-1: Details of the active substances

Active substance	Active substance
Concentration (Unit: g/L)	250 g/L
Chemical group	pyrrolidone
Mode of action	Inhibitor of the phytoene desaturase (MoA Group 12, HRAC 2020)
Biological action	Inhibition of the synthesis of carotenoids which leads to the loss of the protective pigments of the chlorophyll molecules Inhibition of the phytoene desaturase impairs the synthesis of carotenoids, that in healthy plants protect chlorophyll molecules from oxidative damage.
Time of application / type of use	Pre-emergence

Description of the plant protection product

Product AG-F8-250CS (Racer 250 CS) , capsule suspension, contain 250 g/L flurochloridone.

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

Uses		Member State	Requested rate	Comments / Other relevant details on GAPs
Crop	Target(s)			
<i>Solanum tuberosum</i> SOLTU pre emergence	Annual mono and dicotyledonous weed plants Dicotyledonous weed plants and <i>Echinochloa crus-galli</i>	PL	2,0 l/ha, single application per use and per season	Pre-emergence application

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

Description of the target pests

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

EPPO code	Scientific name
AMARE	<i>Amaranthus retroflexus</i>
ECHCG	<i>Echinochloa crus-galli</i>
BRSNW	<i>Brassica napus</i>
SOLNI	<i>Solanum nigrum</i>
CHEAL	<i>Chenopodium album</i>
POLCO	<i>Polygonum convolvulus</i>
POLPE	<i>Persicaria maculosa</i>
VIOAR	<i>Viola arvensis</i>
SPRAR	<i>Spergula arvensis</i>
GERPU	<i>Geranium pusillum</i>
EROCI	<i>Erodium cicutarium</i>
MATIN	<i>Matricaria inodora</i>
STEME	<i>Stellaria media</i>
GALAP	<i>Galium aparine</i>
VERPU	<i>Veronica pulvinaris</i>
CAPBP	<i>Capsella bursa-pastoris</i>
THLAR	<i>Thlapsi arvense</i>
GASPA	<i>Galinsoga parviflora</i>
VIOTR	<i>Viola tricolor</i>
CONAR	<i>Convolvulus arvensis</i>
PAPRH	<i>Papaver rhoeas</i>

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

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
SOLTU /potato	PL	-	Annual mono and dicotyledonous weed plants and <i>Echinochloa crus-galli</i>	PL	-

Compliance with the Uniform Principles

Trials were carried out by testing organisations, all of which followed the available EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The design and analysis of results and reporting of the studies were carried out in compliance with the general EPPO Guidelines PP 1/49(3), PP /135(4), PP 1/181(4), PP 1/152(4)

Information on trials submitted

Table 3.2-5: Presentation of trials (efficacy trials)

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)		GEP, non-GEP, official***	Comments (any other relevant information)
					North-East zone	-		
SOLTU pre – emergence)	Amaranthus retroflexus (AMARE)	Poland	2019	E	1(1)	-	GEP	
	TOTAL	-	2019	-	1(1)	-	-	
SOLTU pre – emergence)	Solanum nigrum (SOLNI)	Poland	2018 2019	E	1(1) 1(1)	-	GEP	
	TOTAL	-	2018- 2019	-	2(2)	-	-	
SOLTU pre – emergence)	Brassica napus (BRSNW)	Poland	2018 2019	E E	1(1) 3(3)	-	GEP	
	TOTAL	-	2018- 2019	-	4(4)	-	-	
SOLTU pre – emergence)	Echinochloa crus galli (ECHCG)	Poland	2018 2019	E E	2(2) 6(6)	-	GEP	
	TOTAL	-	2018- 2019	-	8(8)	-	-	
SOLTU pre – emergence)	Chenopodium Album (CHEAL)	Poland	2018 2019	E	3(3) 6(6)	-	GEP	
	TOTAL	-	2018- 2019	-	9(9)	-	-	
SOLTU pre – emergence)	Polygonum convolvulus (POLCO)	Poland	2018 2019	E	2(2) 2(2)	-	GEP	
	TOTAL	-	2018- 2019	-	4(4)	-	-	
SOLTU pre – emergence)	Persicaria maculosa (POLPE)	Poland	2019	E	3(3)		GEP	
	TOTAL	-	2019	-	3(3)	-	-	
SOLTU pre – emergence)	Viola arvensis (VIOAR)	Poland	2018 2019	E	2(2) 3(3)	-	GEP	
	TOTAL	-	2018- 2019	-	5(5)	-	-	
SOLTU pre – emergence)	Spergula arvensis (SPRAR)	Poland	2018	E	1(1)	-	GEP	
	TOTAL	-	2018	-	1(1)	-	-	
SOLTU pre – emergence)	Geranium pusillum (GERPU)	Poland	2018	E	2(2)	-	GEP	
	TOTAL	-	2018	-	2(2)	-	-	
SOLTU pre – emergence)	Erodium cicutarium (EROCI)	Poland	2018 2019	E	1(1) 1(1)	-	GEP	
	TOTAL	-	2018- 2019	-	2(2)	-	-	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials		GEP, non-GEP	Comments (optional)
SOLTU pre – emergence)	Matricaria inodora (MATIN)	Poland	2019	E	4(4)	-	-	
	TOTAL	-	2019	-	4(4)	-	-	
SOLTU pre – emergence)	Stellaria media (STEME)	Poland	2019	E	5(5)	-	GEP	
	TOTAL	-	2019	-	5(5)	-	-	
SOLTU pre – emergence)	Galium aparine (GALAP)	Poland	2019	E	2(2)	-	GEP	
	TOTAL	-	2019	-	2(2)	-	-	
SOLTU pre – emergence)	Veronica pulvi (VERPU)	Poland	2019	E	1(1)	-	GEP	
	TOTAL	-	2019	-	1(1)	-	-	
SOLTU pre – emergence)	Capsella bursa-pastoris (CAPBP)	Poland	2019	E	3(3)	-	GEP	
	TOTAL	-	2019	-	3(3)	-	-	
SOLTU pre – emergence)	Thlapsi arvense (THLAR)	Poland	2019	E	2(2)	-	GEP	
	TOTAL	-	2019	-	2(2)	-	-	
SOLTU pre – emergence)	Galinsoga parviflora (GASPA)	Poland	2019	E	2(2)	-	GEP	
	TOTAL	-	2019	-	2(2)	-	-	
SOLTU pre – emergence)	Viola tricolora (VIOTR)	Poland	2019	E	2(2)	-	GEP	
	TOTAL	-	2019	-	2(2)	-	-	
SOLTU pre – emergence)	Convolvulus arvensis (CONAR)	Poland	2019	E	2(2) 1(1)	-	GEP	
	TOTAL	-	2019	-	2(2) 1(1)	-	-	
SOLTU pre – emergence)	Papaver rhoeas (PAPRH)	Poland	2019	E	1(1)	-	GEP	
	TOTAL	-	2019	-	1(1)	-	-	
1	21	-	2018-2019	-	11(11)	-	-	

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

Table 3.2-6: Presentation of reference standards used in trials (efficacy trials)

Crop	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
SOLTU/potato	Racer 250 EC	PL	R-8/2003	Flurochloridone	EC	250 g/L	2,0 – 3,0 l/ha	2,0 – 3,0 l/ha	

(1) only on use(s) applied for (with the test product). (2) e.g. WP (wetttable powder), EC (emulsifiable concentrate), etc. (3) dose(s) / dose range authorized on that use in the country. (4) Other relevant information (e.g. uses, number of applications,

spray volume, method of application, etc.).

3.2.1 Preliminary tests (KCP 6.1)

Product contain flurochloridone 250 g/L as Racer (EC) is already registered since several years in Czech Republic, Hungary, Poland, Romania and Slovakia. Its mode of action as well as the range of effective rates is well known. Therefore, no preliminary range-finding tests have been carried out.

3.2.2 Minimum effective dose tests (KCP 6.2)

All efficacy trials of AG-F8-250CS (Racer 250 CS) presented in the dossier were carried out including MED (1,0 l/ha , 1,5 l/ha) compared to requested target dose rate: 2, 0 l/ha. In 2018-2019 there were 11 efficacy field trials conducted including MED.

Mono- and dicotyledonous weed plants in potato (SOLTU)

The aim of conducted efficacy trials was the determination of minimum effective dose rate (MED) for the control of mono- and dicotyledonous weed plants in potato (SOLTU). Product : AG-F8-250CS (Racer 250 CS) was tested at 1,0 ; 1,5 and 2,0 l/ha. The dose rates reflect the proposed label rate: 2,0 l/ha; 50% of the label rate: 1,0 l/ha and 75% of the label rate: 1,5 l/ha, in accordance with the EPPO standard PP 1/225 'Minimum effective dose'.

Table 3.2-7: Minimum effective dose. Efficacy of AG-F8-250CS (Racer 250 CS) at proposed label rate, at 50% and 75% dose rates on target weed plants.

target weed plants	Pest incidence (n trials)	Infestation of the untreated control (unit: PLA/m2)			% control with product AG-F8 250 CS (RACER 250 CS)								
					Rate : 1,0 l/ha (50%)			Rate : 1,5 l/ha (75%)			Rate : 2,0 l/ha (100%)		
		Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
AMARE	1	13,30			70,80	68,30	73,30	81,00	79,50	82,50	91,30	86,80	95,80
SOLNI	2	7,4	5,0	9,8	78,70	52,00	99,80	85,60	72,80	99,80	90,60	81,50	100,00
BRSNW	4	6,40	4,0	8,0	83,70	63,80	99,80	90,70	82,50	99,80	97,70	95,00	100,00
ECHCG	8	9,10	3,0	15,3	51,80	30,00	92,30	64,20	42,50	93,80	70,20	46,50	100,00
CHEAL	9	10,80	6,30	27,80	80,50	42,50	100,00	85,80	46,30	100,00	91,50	58,80	100,00
POLCO	4	9,70	5,50	16,00	66,20	52,50	92,50	79,30	67,50	95,00	85,40	82,50	97,50
POLPE	3	12,70	6,00	23,80	63,30	20,00	100,00	73,80	25,00	100,00	84,60	55,00	100,00
VIOAR	5	11,20	5,80	20,30	62,00	51,30	78,00	75,50	66,30	81,00	83,80	78,80	89,00
SPRAR	1	10,00			78,50	78,00	79,00	91,50	90,00	93,00	95,00	93,00	97,00
GERPU	2	7,50	5,00	11,00	83,40	64,00	99,80	88,80	75,00	100,00	92,30	83,00	100,00
EROCI	2	5,50	5,00	6,00	99,10	97,50	100,00	99,00	98,00	100,00	99,50	99,00	100,00
MATIN	4	6,50	5,00	7,80	91,10	63,70	100,00	95,90	82,50	100,00	99,40	86,30	100,00
STEME	5	6,70	1,00	11,30	73,60	45,00	100,00	81,00	50,00	100,00	91,90	43,80	100,00
GALAP	2	10,40	9,00	12,30	58,80	56,30	62,50	71,60	68,80	73,80	85,30	88,80	82,50
VERPU	1	6,90	6,30	7,50	65,00	61,30	68,80	82,50	81,30	83,80	97,50	97,50	97,50
CAPBP	3	6,80	5,50	9,30	83,80	75,00	100,00	90,70	75,00	100,00	93,30	75,00	100,00
THALR	2	9,50	6,00	9,50	88,10	76,30	100,00	92,60	85,30	100,00	97,50	95,00	100,00
GASPA	2	9,50	5,80	14,00	100,00			100,00			100,00		
VIOTR	2	4,70	2,00	7,50	76,60	48,00	100,00	78,40	52,00	100,00	90,90	70,80	100,00
CONAR	2	11,90	9,50	14,00	84,10	62,50	100,00	97,50	92,50	100,00	98,20	95,30	100,00
PAPRH	1	1,5			62,50	50,00	75,00	50,00	50,00	50,00	87,50	75,00	100,00

Comments of zRMS:

The applicant provided no information on the assessment dates on which the summary in the Table 3.2-9 is based. According to EPPO guidance PP 1/51 (3) *Weeds in potato*, the first assessment should be made at the crop BBCH stage 12-14, and the second one – 2 weeks later. Therefore the zRMS summarized the efficacy for the MED according to the PP 1/51 (3), compiling those data that approach as much as possible the crop stages and time intervals given in the guidance. The MED summary is thus presented below in the alternative Table 3.2-9 - at crop BBCH 12-14 (9-39 DAA).

Table 3.2-9 a that follows, represents the later assessment interval: 19-53 DAA *i.e.* 10-14 days after the first assessment (BBCH 12-61). It is one of the two intervals selected by the applicant for efficacy summary in the next chapter.

Table 3.2-9: Minimum effective dose. Efficacy of AG-F8-250CS (Racer 250 CS) at proposed label rate 2.0 L/ha and at 75% and 50% of the target dose rate. BBCH crop: 12-14; 9-39 DAA.

treat- ment	UNCK PLA/m2			AGF-F8-250 CS								
dose rate	0			1,0 L/ha			1,5 L/ha			2,0 L/ha		
AMARE	11	-	-	56,3	-	-	67,5	-	-	80,8	-	-
n	1			1			1			1		
BRSNW	6,3	5,5	8,0	73,5	61,3	85,8	82,3	76,3	88,3	97,4	97,3	97,5
n	4			2			2			2		
CAPBP	5,9	4,5	8,3	88,1	76,3	100,0	91,9	83,8	100,0	96,9	93,8	100,0
n	4			2			2			2		
CHEAL	10,7	6,0	25,5	76,1	26,3	100,0	82,8	35,0	100,0	88,5	41,3	100,0
n	9			7			7			7		
CONAR	9,5	-	-	93,8	-	-	87,5	-	-	97,5	-	-
n	1			1			1			1		
ECHCG	7,8	5,0	13,0	68,2	27,5	92,5	75,2	32,5	100,0	87,9	73,8	100,0
n	8			7			7			7		
EROCI	31,9	5,0	58,8	100,0	100,0	100,0	99,5	99,0	100,0	99,5	99,0	100,0
n	2			2			2			2		
GALAP	10,6	9,0	12,3	60,0	-	-	72,5	-	-	82,5	-	-
n	2			1			1			1		
GASPA	14,0	-	-	100,0	-	-	100,0	-	-	100,0	-	-
n	1			1			1			1		
GERPU	6,0	5,0	7,0	81,0	-	-	84,0	-	-	90,0	-	-
n	2			1			1			1		
MATIN	6,1	5,0	7,5	81,9	63,7	100,0	87,5	75,0	100,0	98,1	96,2	100,0
n	4			2			2			2		
POLCO	8,9	5,5	12,0	76,4	48,8	93,8	84,0	62,5	97,5	88,9	73,8	100,0
n	4			4			4			4		
POLPE	10,0	6,0	15,8	50,0	17,5	82,5	63,8	27,5	100,0	75,0	50,0	100,0
n	3			2			2			2		
SOLNI	5,0	5,0	5,0	51,3	-	-	62,5	-	-	81,3	-	-
n	2			1			1			1		
SPRAR	10,0	-	-	74,0	-	-	86,0	-	-	90,0	-	-
n	1			1			1			1		
STEME	8,1	6,0	11,3	80,4	62,5	100,0	87,1	78,8	100,0	97,5	96,3	100,0
n	4			3			3			3		
THLAR	7,8	6,0	9,5	78,8	-	-	82,5	-	-	95,0	-	-
n	2			1			1			1		
VERPU	6,3	-	-	67,5	-	-	81,3	-	-	98,8	-	-
n	1			1			1			1		
VIOAR	10,9	5,8	20,3	66,9	45,0	89,0	76,9	61,3	91,0	83,3	72,5	90,0
n	5			4			4			4		
VIOTR	4,8	2,0	7,5	100,0	-	-	100,0	-	-	100,0	-	-
n	2			1			1			1		

* n – number of trials

Table 3.2-9 a: Minimum effective dose. Efficacy of AG-F8-250CS (Racer 250 CS) at proposed label rate 2.0 L/ha and at 75% and 50% of the target dose rate. BBCH crop: 12-61; 19-53 DAA.

treatment	UNCK PLA/m2			AGF-F8-250 CS								
dose rate	0			1,0 L/ha			1,5 L/ha			2,0 L/ha		
AMARE	13,3	-	-	68,3	-	-	79,5	-	-	86,8	-	-
n	1			1			1			1		
BRSNW	6,4	4,0	8,0	83,8	63,8	99,8	90,9	82,5	99,8	98,3	97,0	100,0
n	4			4			4			4		
CAPBP	7,0	5,5	9,3	87,9	77,5	100,0	94,8	86,3	100,0	97,9	93,8	100,0
n	4			3			3			3		
CHEAL	12,8	6,5	27,8	82,2	42,5	100,0	86,7	46,3	100,0	91,9	58,8	100,0
n	9			9			9			9		
CONAR	9,5	-	-	73,8	-	-	82,5	-	-	95,3	-	-
n	1			1			1			1		
ECHCG	9,2	4,5	15,3	60,2	30,0	90,0	65,0	42,5	93,8	73,5	47,5	100,0
n	8			8			8			8		
EROCI	5,4	5,0	5,8	99,5	99,0	100,0	99,0	98,0	100,0	99,5	99,0	100,0
n	2			2			2			2		
GALAP	10,6	9,0	12,3	59,4	56,3	62,5	72,5	71,3	73,8	85,6	82,5	88,8
n	2			2			2			2		
GASPA	9,9	5,8	14,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0	100,0
n	2			2			2			2		
GERPU	8,0	5,0	11,0	81,9	64,0	99,8	87,5	75,0	100,0	93,0	86,0	100,0
n	2			2			2			2		
MATIN	6,6	5,0	7,8	90,2	65,0	100,0	95,6	82,5	100,0	99,7	98,8	100,0
n	4			4			4			4		
PAPRH	1,5	-	-	50,0	-	-	50,0	-	-	75,0	-	-
n	1			1			1			1		
POLCO	9,4	6,8	12,0	71,0	52,5	92,5	82,6	73,0	95,0	87,8	83,8	97,5
n	4			4			4			4		
POLPE	12,8	6,0	23,8	59,2	20,0	100,0	75,8	27,5	100,0	85,0	55,0	100,0
n	3			3			3			3		
SOLNI	5,5	5,0	6,0	78,1	56,3	99,8	84,7	69,5	99,8	91,9	83,8	100,0
n	2			2			2			2		
SPRAR	10,0	-	-	78,0	-	-	90,0	-	-	93,0	-	-
n	1			1			1			1		
STEME	8,3	6,0	11,3	81,0	67,5	100,0	89,4	83,8	100,0	98,7	96,3	100,0
n	4			4			4			4		
THLAR	7,8	6,0	9,5	88,1	76,3	100,0	92,6	85,3	100,0	97,5	95,0	100,0
n	2			2			2			2		
VERPU	6,3	-	-	68,8	-	-	83,8	-	-	97,5	-	-
n	1			1			1			1		
VIOAR	11,3	5,8	20,3	61,3	53,8	70,0	76,3	73,8	80,0	83,8	80,0	89,0
n	5			5			5			5		
VIOTR	7,5	-	-	72,9	58,3	87,5	70,4	61,5	79,3	96,4	92,8	100,0
n	1			2			2			2		

* n – number of trials

Summary and conclusions on the minimum effective dose

According to the presented results, the recommended target dose rate 2,0 l/ha provided the best overall control and should be considered most effective against mono- and dicotyledonous weed plants in potato (SOLTU), for which the activity of AG-F8-250CS (Racer 250 CS) is claimed.

Comments of zRMS on the Minimum Effective Dose:

During the first assessments, 9-39 DAA, at the crop stage BBCH 12-14 (Table 3.2-9) the dose response was clearly visible in all weed species except EROCI, GASPA and VIOTR, for which the 1,0 L/ha dose rate was already effective (in GASPA and VIOTR these results are concluded based on a single trial and should be treated with caution).

The same is true within the second interval, 19-53 DAA (BBCH 12-60, Table 3.2-9 a). The dose response was more apparent between the 1,5 and 2,0 L/ha dose rates compared to 1,0 L/ha *versus* 1,5 L/ha, within both assessment intervals. With two exceptions only, wherever the efficacy exceeded 95% it was achieved by the target dose rate alone. Therefore the dose rate 2,0 L/ha of the test item AG-F8-250 CS may be considered as the proper minimum effective dose rate against majority of the weed species for which the label claim is made.

3.2.3 Efficacy tests (KCP 6.2)

Materials and methods

Eleven efficacy trials were conducted in 2018-2019, to determine efficacy of product AG-F8-250CS (Racer 250 CS) against mono and dicotyledonous weed plants in potato (SOLTU). All trials were conducted in Poland (North-East Zone), in different edaphic/climatic conditions typical for the protected tested crop plant.

Site

Trials were conducted in regions where potato is grown commercially. The experiment was established on a set of complete randomized blocks in 4 replications.

Testing units:

- 1). Fertico Sp. z o.o.
- 2). Eurofins Agroscience Services Sp. z o.o.
- 3). Agreco Sp z o.o.
- 4).Uniwersytet Przyrodniczy in Augusta Cieszkowskiego
- 5).Staphyt Sp z o.o.

The testing units have been mandated to conduct research in the field of efficacy of plant protection products and are officially GEP recognized.

Experimental details

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:

1. PP 1/135 (4) Phytotoxicity assessment;
2. PP 1/152 (4) Design and analysis of efficacy evaluation trials;
3. PP 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice.
4. PP 1/51(3) Weeds in potato

Assessment methods

Statistical Analysis

In case of statistical analysis, Data were analysed using a two-way analysis of variance (ANOVA). The probability of non-significant differences occurring between treatment means is calculated as the F probability value (Prob(F)). Student-Newman-Keuls test was then applied to separate any treatment differences that may be implied by the ANOVA TEST (Prob(F)<0.05) and these are indicated by the

LSD-value and by a letter-test. Statistical analysis was carried out with the use of statistic pack of ARM Research Manager 9 Software (Gylling Data Management).

Assessment of efficacy

The assessment of efficacy in the treated plots was made in relation to the untreated plot on an overall plot basis (scale 0-100 %, 0 % =no efficacy). The assessment date was determined by the speed of action and period of efficacy of the test items.

The number of weeds/m² was counted in 5 x 0,1 m² quadrats with the measuring scale 'Göttinger Zähl- und Schätzrahmen'. The coverage level (ground cover) of the weed population by species was assessed by visual estimation using a scale 0-100 % (100 %=total ground cover).

Evaluation of weed: number of weeds /m² – untreated plots

Efficacy was assessed for each weed species based on the evaluation of weed destruction comparable to control plots in percentage scale from “0” to “100”, in which “0” meant no damage whereas “100” meant

a total damage found.

Evaluation of weed control consisted of 3 elements:

determination of the number of weeds /m² – in the untreated plots,

assessment of the % surface coverage for each weed species – in the untreated plots,

The assessment of the visual efficacy of weed control for each individual weeds.

determination of the number of weeds /m² – in the untreated plots,

assessment of the % surface coverage for each weed species – in the untreated plots,

Assessment of the visual efficacy of weed control for each individual weeds.

Assessment of phytotoxicity

Phytotoxicity (chlorosis and necrosis), stunting and thinning were assessed by visual estimation of the intensity on an overall plot basis on a percentage scale 0-100 % (0=no damage). The assessment date was determined by the speed of action and period of efficacy of the test substances. Phytotoxicity was assessed in percentage scale from “0” to “100”, in which “0” meant no damage whereas “100” meant a total damage found.

Selectivity: visual estimation of phytotoxicity according to scale 0-100%).

Applications methods and rates

The application were conducted with knapsack sprayer / compressed air plot sprayer, and Schachtner SPRBIC.

The tested product was applied according to the treatment list :

Name	Rate (kg, l/ha)	Other rate (g a.s./ha)	Appl Code	Growth stage (BBCH)
Untreated Check				
AG-F8-250CS (RACER 250 CS)	1	250	A	BBCH 00-09
AG-F8-250CS (RACER 250 CS)	1,5	375	A	BBCH 00-09
AG-F8-250CS (RACER 250 CS)	2	500	A	BBCH 00-09
RACER 250 EC	1,5	375	A	BBCH 00-09
RACER 250 EC	2	500	A	BBCH 00-09

Table 3.2-8: Details on trial methodology

Guidelines	General guidelines	PP 1/135(4) PP 1/181(4) PP 1/152(4)
	Specific guidelines	PP 1/51(3)
Experimental design	Plot design	RCBD
	Plot size	19,6 -28,0 m ²
	Number of replications	4
Crop	Trials per crop	Potato (SOLTU) - 11
	Varieties per crop	Innovator, Denar, Tomensa, Albatros, Gala, Lilly, Toskana , Natasha, Soraya, Zuzanna
	Planting dates	28.04.2018 30.04.2018 21.04.2018 12.04.2019 28.04.2019 30.04.2019 29.04.2019 22.04.2019 08.05.2019 12.04.2019 06.05.2019
Application	Crop stage (BBCH)* at application	BBCH 00-09 00-08
	Timing Pest stage at application (1)	Pre-emergence BBCH 00: AMARE, SOLNI, BRSNW, ECHCG, CHEAL, POLCO, POLPE, VIOAR, SPRAR, GERPU, EROCI, MATIN, STEME, GALAP, VERPU, CAPBP, THLAR, GASPA, VIOTR, CONAR.
	Number of applications Intervals between applications	1
	Spray volumes	200 L/ha or 250 L/ha
Assessment	Assessment types	% of weed coverage, number of weeds/m ²
	Assessment dates	DAA (days after application A) 0;9;11;13;15;16;19;20;22;25;27;28;29;30;31;32;33;34;36;39;41;42;43;45;52;53;54;59;60 Assessment intervals: DAA 9-39 (MED) DAA 19-53 DAA 32-60
Other relevant information	e.g. Soil type, pH	Sand, sandy loam, silt loam, clayey sand, calcareous clay, sandy clay loam, loamy sand, pH: 5,8; 6,4; 6,0; 6,1; 6,6; 6,5; 6,9; 5,1
	e.g. Natural / artificial inoculation	N
	e.g. Field / Greenhouse	F

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

Mono – and dicotyledonous weed plants in potato (SOLTU)

Total of 11 efficacy trials were carried out in 2018-2019, to determine efficacy of product : AG-F8-

250CS (Racer 250 CS) in controlling mono and dicotyledonous weed plants in potato (SOLTU). The trials were conducted in 2018 and 2019 in Poland (North East Zone) . Efficacy data are presented in tables below (3.2-11 and 3.2.-12)

Comments of zRMS:

The applicant has calculated average efficacy for individual weed species by sampling the efficacy values twice: from two consecutive assessments from each trial. The results of this calculation are presented in BAD and are summarized in the dRR as the Table 3.2-11. zRMS considers this way of data summarizing inappropriate. Instead, each individual trial should be sampled only once for each summary concerning particular time interval after the application.

The efficacy values in the Table 3.2-11 have been corrected by zRMS where necessary, according to the proper calculation based on a single data point from any trial, within an assessment interval. The number of trials has been corrected where inadequate weed infestation was reported from individual trials, or if the species was in fact found to be missing from the respective trial report, quoted explicitly by its number (one such instance was noted).

The efficacy assessment intervals proposed by the applicant are shown in the separate tables now:

Table 3.2-11 a (19-53 DAA) and Table 3.2-11 b (32-60 DAA).

According to the dataset delivered by the applicant, the crop growth stages recorded in the trial reports are within BBCH 12-61 on all dates included in both the assessment intervals: 19-53 and 32-60 DAA.

Table 3.2-11 a: Efficacy of product AG-F8-250CS (Racer 250 CS) calculated at 19-53 DAA (BBCH 12-61).

Target	Number of trials	Infestation in the untreated control (unit:PLA/m2))		% control		% control	
				AG-F8-250CS (Racer 250 CS) - 2,0 l/ha		Racer 250 EC 2,0 l/ha	
		Mean	Min - Max	Mean	Min - Max	Mean	Min - Max
assessments : 19-53 DAA (11 trials)							
SOLNI	2	5,5	5,0-6,0	91,9 %	83,8% - 100,0%	92,4%	84,8% - 100,0%
BRSNW	4	6,5	5,5-8	97,12%	96,0%-100,0 %	92,92%	95,0%-100,0%
BRSNW	4	6,4	4,0-8,0	98,3%	97,05 - 100,0%	89,6%	62,3%-100,0%
ECHCG	8	8,9	4,8-15,3	75,10%	47,5%-100,0%	83,16 %	60,0%-100,0%
ECHCG	8	9,2	4,5-15,3	73,4%	47,5% - 100,0%	81,5%	60,0%-100,0%
CHEAL	9	12,15	6,3-27,8	92,65%	58,8%-100,0%	92,28%	91,0 % -100,0%
CHEAL	9	12,8	6,5-27,8	91,9%	58,8% - 100,0%	97,3%	90,0%-100,0%
POLCO	4	12	5,5-11	89,0 %	82,5% - 97,5%	93,45%	83,8%-100,0%
POLCO	4	9,4	6,8-12,0	87,8%	83,8% - 97,5%	93,1%	86,3%-100,0%
POLPE	3	12,7	6 -23,8	85,00%	55,0% - 100,0%	92,50% 90,4%	77,5% -100,0%
VIOAR	5	10,8	5,8-19,8	84,42%	78,8%-89,0%	89,02%	82,5%-100,0%
VIOAR	5	11,3	5,8-20,3	83,8%	80,0% - 89,0%	89,1%	83,0 - 100,0%
SPRAR	1	10	10	97,0%	97,0%	100,0%	100,0%
GERPU	2	7	5 - 9	93,0%	86,0%-100,0%	93,00%	86,0%-100,0%
EROCI	2	5,5	5 - 6	99,5%	99,0% - 100,0%	100,00%	100,0%
MATIN	4	6,45	6-7,5	99,05%	96,2%-100,0%	96,55%	87,5%-100,0%
MATIN	4	6,6	5,0-7,8	99,7%	98,8% - 100,0%	97,6%	91,8% - 100,0%
STEME	5	6,56	1-11,3	96,40%	90,0%-100,0 %	93,46%	72,5 % -100,0%

Target	Number of trials	Infestation in the untreated control (unit:PLA/m2))		% control		% control	
				AG-F8-250CS (Racer 250 CS) - 2,0 l/ha		Racer 250 EC 2,0 l/ha	
		Mean	Min - Max	Mean	Min - Max	Mean	Min - Max
STEME	4	8,3	6,0 - 11,3	98,7%	96,3% - 100,0%	99,0%	96,3% - 100,0%
GALAP	2	10,25	9 - 11,5	85,00%	82,5% - 87,5%	86,90%	85,0% - 88,8%
GALAP	2	10,6	9,0 - 12,3	85,6%	82,5% - 88,8%	88,1%	87,5% - 88,8%
VERPU	1	6,3	6,3	97,5%	97,50%	100,0%	100,00%
CAPBP	3	6,76	5,5 - 9,3	89,56%	75,0% - 99,9%	91,23%	75,0% - 99,9%
CAPBP	3	7,0	5,5 - 9,3	97,9%	93,8% - 100,0%	99,6%	98,8% - 100,0%
THLAR	2	7,7	6 - 9,5	97,5%	95,0% - 100,0%	98,15%	96,3% - 100,0%
GASPA	2	8,9 9,9	5,8 - 12 14	100,0%	100,0%	100,0%	100,0%
VIOTR	2	4,75	2 - 7,5	85,40%	70,8% - 100,0%	85,00%	70,0% - 100,0%
VIOTR	1	7,5	-	100,0%	-	100,0%	-
CONAR	2	10,75	9,5 - 12	98,75%	97,5% - 100,0%	100,00%	100,00%
CONAR	1*	9,5	-	95,3%	-	90,8%	-
PAPRH	1	1,5	1,5	100,00% 75%	100,00%	65,00% 50%	65,00%

* CONAR is reported in BAD from trials PL19HESOLTU031E and PL19HESOLTU031G, but can be found only in PL19HESOLTU031E trial report

Table 3.2-11 b: Efficacy of product AG-F8-250CS (Racer 250 CS) calculated at 32-60 DAA (BBCH 12-61).

Target	Number of trials	Infestation in the untreated control (unit:PLA/m2)		% control		% control	
				AG-F8-250CS (Racer 250 CS) - 2,0 l/ha		Racer 250 EC 2,0 l/ha	
		Mean	Min - Max	Mean	Min - Max	Mean	Min - Max
assessments : 32-60 DAA (11 trials)							
SOLNI	2	5,5	5-6	94%	88,0% -100,0%	95,4 %	90,8 % -100,0 %
BRSNW	4	6,3	4-8	98,3%	97,0%-100,0%	89,7%	62,3%-100,0%
ECHCG	8	9,2	5,3-15,3	73,1%	46,5%-100%	80,8%	63,8%-100,0%
CHEAL	9	12,9	6,5-27,8	92.2%	62,0 %-100,0%	97,2%	90,0%-100,0%
POLCO	4	10,45	6,8-16	87,8%	83,5%-97,5%	91,8%	86,0%-100,0%
POLPE	3	12,76	6-23,8	84,2%	57,5%-100,0%	89,8%	79,5%-100,0 %
VIOAR	5	11,58	7-20,3	83,2%	80,0%-87,5%	88,9%	83,0%-99,0%
SPRAR	1	10	10	93,0%	93,00%	95,0%	95,00%
GERPU	2	8	5-11	91,5%	83,0%-100,0%	92,5%	85,0%-100,0%
EROCI	2	5,4	5,0-5,8	99,5%	99,0%-100,0%	100,0%	100,0%
MATIN	4	6,57	5-7,8	99,7%	98,8%-100,0%	98,2%	93,8%-100,0%
STEME	5	6,56	4 - 11,3	87,50%	43,8% - 100,0 %	89,10%	49,3% - 100,0%
STEME	4	8,3	6,0-11,3	98,4%	95,0%-100,0%	98,7%	95,0%-100,0%
GALAP	2	12,65	9- 12,3	85,7%	82,5% - 88,8 %	88,2%	87,5% - 88,8 %
VERPU	1	7,5	7,5	97,5%	97,50%	97,5%	97,50%
CAPBP	3	6,76	5,5 -9,3%	97,1%	91,3% - 100,0%	99,6%	98,8% - 100,0%

Target	Number of trials	Infestation in the untreated control (unit:PLA/m2)		% control		% control	
				AG-F8-250CS (Racer 250 CS) - 2,0 l/ha		Racer 250 EC 2,0 l/ha	
		Mean	Min - Max	Mean	Min - Max	Mean	Min - Max
THLAR	2	7,7	6-9,5	97,5%	95,0%-100,0%	98,2%	96,3%-100,0%
GASPA	2	10	14-cze	100,0%	100,00%	100,0%	100,00%
VIOTR	2	4,69	2-7,3	96,4%	92,8% -100,0%	84,4%	68,8%-100,0 %
CONAR	2	11,9	9,8-14	97,69%	95,3% -100,0%	95,40%	90,8% -100,0 %
CONAR	1*	9,5	-	95,3%	-	90,8%	-
PAPRH	1	1,5	1,5	75,0%	75,00%	50,0%	50,00%
AMARE TRIAL: PL19HESOLTU031A							
AMARE 53 DAA	2	13,3		86,8%		96,5%	
AMARE 60 DAA		13,3		95,8%		99,3%	

* CONAR is reported in BAD from trials PL19HESOLTU031E and PL19HESOLTU031G, but can be found only in PL19HESOLTU031E trial report

Comments of zRMS:

There is no apparent indication in the present document or in the BAD, on the origin of the efficacy values in the following Table 3.2-12. As the averaging of any results without defining clearly the assessment interval is inappropriate and the above data summary - in Table 3.2-11 a and b - already includes two intervals, the zRMS considers the following Table 3.2-12 as redundant. The information contained in it does not contribute, in any significant degree, to the weed classification resulting from the data presented in the previous summaries.

Table 3.2-12: Efficacy of product AG-F8-250CS (Racer 250 CS) calculated average per cent efficacy across all trials.

Target	CROP	Number	Infestation in the untreated control (unit:PLA/m2))		% control		% control	
					AG-F8-250CS (Racer 250 CS) - 2,0 l/ha		Racer 250 EC 2,0 l/ha	
			Mean	Min - Max	Mean	Min - Max	Mean	Min - Max
AMARE	SOLTU	1	13,3	-	91,30%	86,8% - 95,8 %	97,80%	96,5 % - 99,3%
SOLNI	SOLTU	2	5,5	5,0 - 9,8	90,60%	81,5% - 100,0 %	91,90%	85 % - 100,0%
BRSNW	SOLTU	4	6,4	4,0 - 8,0	97,70%	95% - 100,0%	91,30%	62,3% - 100,0%
ECHCG	SOLTU	8	9,1	4,8 - 15,3	70,20%	46,5% - 100%	80,10%	60,0% - 100,0%
CHEAL	SOLTU	9	10,8	6,3 - 27,8	91,50%	59,8% - 100,0%	96,90%	90,0% - 100,0%
POLCO	SOLTU	4	9,7	5,5 - 16,0	85,40%	82,5% - 97,5%	90,20%	83,8% - 100,0%
POLPE	SOLTU	3	12,7	6,0 - 23,8	86,60%	55% - 100,0%	91,20%	77,5% - 100,0%
VIOAR	SOLTU	5	11,2	5,8 - 20,3	83,80%	78,8% - 89,0%	89,00%	82,5% - 100,0%
SPRAR	SOLTU	1	10	-	95,00%	93,0% - 97,0%	97,50%	95,0% - 100,0%
GERPU	SOLTU	2	7,5	5,0 - 11,0	92,30%	83,0% -	92,80%	85,0% - 100,0%

Target	CROP	Number	Infestation in the untreated control (unit:PLA/m ²)		% control		% control	
					AG-F8-250CS (Racer 250 CS) – 2,0 l/ha		Racer 250 EC 2,0 l/ha	
			Mean	Min–Max	Mean	Min–Max	Mean	Min–Max
						100,0%		
EROCI	SOLTU	2	5,5	5,0–6,0	99,50%	99,0%–100,0%	100,00%	100,0%
MATIN	SOLTU	4	6,5	5,0–7,8	99,40%	87,5%–100,0%	97,30%	91,8%–100,0%
STEME	SOLTU	5	6,7	1,0–11,3	91,90%	43,8%–100,0%	91,30%	49,3%–100,0%
GALAP	SOLTU	2	10,4	9,0–12,3	85,30%	88,8%–82,5%	87,50%	85,0%–88,8%
VERPU	SOLTU	1	6,9	6,3–7,5	97,50%	98%	98,80%	97,5%–100,0%
CAPBP	SOLTU	3	6,8	5,5–9,3	93,30%	75,0%–100,0%	95,40%	75,0%–100,0%
THLAR	SOLTU	2	9,5	6,0–9,5	97,50%	95,0%–100,0%	98,10%	96,3%–100,0%
GASPA	SOLTU	2	9,5	5,8–14	100,00%	—	100,00%	—
VIOTR	SOLTU	2	4,7	2,0–7,5	90,90%	70,8%–100%	81,80%	69,8%–100%
CONAR	SOLTU	2	11,9	9,5–14,0	98,20%	95,3%–100%	97,70%	90,8%–100%
PAPRH	SOLTU	1	1,5	1,5–1,5	87,50%	75,0%–100,0%	57,50%	50,0%–65,0%

Efficacy data obtained from field trials are presented in tables in two alternative ways: data grouped into 2 assessment intervals, including all trials (Table 3.2-11) and efficacy data presented as average per cent (Table 3.2-12). Results are comparable and can be used to specify label recommendations for product AG-F8-250CS (Racer 250 CS).

Efficacy data obtained from the field trials are grouped into 2 assessment intervals including all trials (Tables 3.2-11 a and Table 3.2-11 b). The results can be used to specify label recommendations for product AG-F8-250CS (Racer 250 CS).

Summary

The submitted efficacy data (reports from field trials) and additional information fulfill requirements and conditions determined in the following EPPO guidelines:

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 good experimental practice.

PP 1/50 (3) Weeds in potato

The studies fulfill also requirements of the Commission Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products. The applicant submitted 11 reports (in total) showing the results in research into product efficacy carried out in 2018 and 2019 in potato (SOLTU). The obtained data in performed trials show that AG-F8-250CS (Racer 250 CS) provides benefits against the most important weeds in potato, as shown in the table 3.2-14 below.

Table 3.2 -13 describes susceptibility classification of weed plants depending on effectiveness of their control by herbicide , according to SANCO /10055/2013 Rev.4 from 3 October 2013.

Table 3.2-13

HS (Highly susceptible)	95-100%
S (Susceptible)	85-94,9%
MS (Moderately Susceptible)	70-84,9%
MT (Moderately Tolerant)	50-69,9%
T (Tolerant)	0-49,9%

Comments of zRMS:

The following Table 3.2-14 originally demonstrates weed susceptibility classification based on the preceding Table 3.2-12. As there is no apparent indication in the present document or in the BAD, on the origin of the efficacy values in the Table 3.2-12, the zRMS considers the following Table 3.2-14 as redundant too. The susceptibility classification presented in the (amended) Table 3.2-15 a (page 25) is based on the preceding summary tables: **Table 3.2-11 a** and **Table 3.2-11 b**.

~~Table 3.2 –14: Average susceptibility classification depending on the effectiveness of their control by a herbicide of weed plants in potato (SOLTU)~~

Product dose kg/ha	Crop	Eppo code	Scientific name	DAA	Average efficacy after application A	Efficacy
AG-F8-250CS (RACER 250 CS) 1,0 l/ha	SOLTU	AMARE	Amaranthus retroflexus	53 ; 60	70,80	MS
		SOLNI	Solanum nigrum	20 ; 34; 53;60	78,70	MS
		BRSNW	Brassica napus	20;34;25;42;29;39;33;43	83,70	MS
		ECHCG	Echinochloa crus-galli	25;27;28;31;33;36;41;42;43;45;53;59;60	51,80	MT
		CHEAL	Chenopodium album	20;25;27;28;30;32;33;36;41;42;43;45;53;54;59;60	80,50	MS
		POLCO	Polygonum convolvulus	27;25;36;41;45;59	66,20	MT
		POLPE	Polygonum maculosa	28;31;36;42;53;58	63,30	MT
		VIOAR	Viola arvensis	27;25;29;30;39;41;42;45;54	62,00	MT
		SPRAR	Spergula arvensis	27;41	78,50	MS
		GERPU	Geranium pusillum	20;27;34;45	83,40	MS
		EROCI	Erodium cicutarium	19;27;33;45	99,10	HS
		MATIN	Matricaria inodora	15;22;25;28;31;36;42	91,10	S
		STEME	Stellaria media	22;25;29;30;33;36;39;43;54	73,60	MS
		GALAP	Galium aparine	29;30;39;54	58,80	MT
		VERPU	Veronica pulvi	25;42	65,00	MT
		CAPBP	Capsella bursa-pastoris	29;30;33;39;43;54	83,80	MS
		THALR	Thlapsi arvense	28;30;36;54	88,10	S
		GASPA	Galinsoga parviflora	42;36;52;59	100,00	HS
		VIOTR	Viola tricolora	31;42;44;61	76,60	MS
		CONAR	Convolvulus arvensis	31;36;42;59	84,10	MS
		PAPRH	Papaver rhoeas	44;61	62,50	MT

AG-F8-250CS (RACER 250 CS) 1,5 l/ha	SOLTU	AMARE	Amaranthus retro- flexus	53 ; 60	81,00	MS
		SOLNI	Solanum nigrum	20 ; 34; 53;60	85,60	S
		BRSNW	Brassica napus	20;34;25;42;29; 39;33;43	90,70	S
		ECHCG	Echinochloa crus- galli	25;27;28;31;33;36;41;42;43;45;53;59;60	64,20	MT
		CHEAL	Chenopodium album	20;25;27;28;30; 32;33;36;41;42; 43;45;53;54;59;60	85,80	S
		POLCO	Polygonum convolvulus	27;25;36;41;45; 59	79,30	MS
		POLPE	Polygonum macu- losa	28;31;36;42;53;58	73,80	MS
		VIOAR	Viola arvensis	27;25;29;30;39; 41;42;45;54	75,50	MS
		SPRAR	Spergula arvensis	27;41	91,50	S
		GERPU	Geranium pusillum	20;27;34;45	88,80	S
		EROCI	Erodium cicutarium	19;27;33;45	99,00	HS
		MATIN	Matricaria inodora	15;22;25;28;31;36;42	95,90	HS
		STEME	Stellara media	22;25;29;30;33; 36;39;43;54	81,00	MS
		GALAP	Galium aparine	29;30;39;54	71,60	MS
		VERPU	Veronica pulvi	25;42	82,50	MS
		CAPBP	Capsella bursa- pastoris	29;30;33;39;43;54	90,70	S
		THALR	Thlapsi arvense	28;30;36;54	92,60	S
		GASPA	Galinsoga parviflo- ra	42;36;52;59	100,00	HS
		VIOTR	Viola tricolora	31;42;44;61	78,40	MS
		CONAR	Convolvulus arven- sis	31;36;42;59	97,20	HS
AG-F8-250CS (RACER 250 CS) 2,0 l/ha	SOLTU	PAPRH	Papaver rhoeas	44;61	50,00	MT
		AMARE	Amaranthus retro- flexus	53 ; 60	91,30	S
		SOLNI	Solanum nigrum	20 ; 34; 53;60	90,60	S
		BRSNW	Brassica napus	20;34;25;42;29; 39;33;43	97,70	HS
		ECHCG	Echinochloa crus- galli	25;27;28;31;33;36;41;42;43;45;53;59;60	70,20	MS
		CHEAL	Chenopodium album	20;25;27;28;30; 32;33;36;41;42; 43;45;53;54;59;60	91,50	S
		POLCO	Polygonum convolvulus	27;25;36;41;45;59	85,40	S
		POLPE	Polygonum macu- losa	28;31;36;42;53;58	84,60	MS
		VIOAR	Viola arvensis	27;25;29;30;39; 41;42;45;54	83,80	MS
		SPRAR	Spergula arvensis	27;41	95,00	HS
		GERPU	Geranium pusillum	20;27;34;45	92,30	S
		EROCI	Erodium cicutarium	19;27;33;45	99,50	HS
		MATIN	Matricaria inodora	15;22;25;28;31;36;42	99,40	HS
		STEME	Stellara media	22;25;29;30;33; 36;39;43;54	91,90	S
		GALAP	Galium aparine	29;30;39;54	85,30	S
		VERPU	Veronica pulvi	25;42	97,50	HS
		CAPBP	Capsella bursa- pastoris	29;30;33;39;43;54	93,30	S

		THALR	Thlapsi arvense	28;30;36;54	97,50	HS
		GASPA	Galinsoga parviflo- ra	42;36;52;59	100,00	HS
		VIOTR	Viola tricolora	31;42;44;61	90,90	S
		CONAR	Convolvulus arven- sis	31;36;42;59	98,20	HS
		PAPRH	Papaver rhoeas	44;61	87,50	S
RACER 250-EC 1,5 l/ha	SOLTU	AMARE	Amaranthus retro- flexus	53 ; 60	90,80	S
		SOLNI	Solanum nigrum	20 ; 34; 53;60	87,80	S
		BRSNW	Brassica napus	20;34;25;42;29; 39;33;43	87,00	S
		ECHCG	Echinochloa crus- galli	25;27;28;31;33;36;41;42;43;45;53;59;60	63,30	MT
		CHEAL	Chenopodium album	20;25;27;28;30; 32;33;36;41;42; 43;45;53;54;59; 60	90,4	S
		POLCO	Polygonum convolvulus	27;25;36;41;45;59	77,30	MS
		POLPE	Polygonum macu- losa	28;31;36;42;53;58	78,30	MS
		VIOAR	Viola arvensis	27;25;29;30;39; 41;42;45;54	77,30	MS
		SPRAR	Spergula arvensis	27;41	90,50	S
		GERPU	Geranium pusillum	20;27;34;45	90,40	S
		EROCI	Erodium cicutarium	19;27;33;45	100,00	HS
		MATIN	Matricaria inodora	15;22;25;28;31 36;42	93,40	S
		STEME	Stellara media	22;25;29;30;33; 36;39;43;54	82,70	MS
		GALAP	Galium aparine	29;30;39;54	74,10	MS
		VERPU	Veronica pulvi	25;42	84,40	MS
		CAPBP	Capsella bursa- pastoris	29;30;33;39;43;54	87,90	S
		THALR	Thlapsi arvense	28;30;36;54	92,70	S
		GASPA	Galinsoga parviflo- ra	42;36;52;59	100,00	HS
		VIOTR	Viola tricolora	31;42;44;61	87,40	S
		CONAR	Convolvulus arven- sis	31;36;42;59	93,10	S
		PAPRH	Papaver rhoeas	44;61	37,50	T
RACER 250-EC 2,0 l/ha	SOLTU	AMARE	Amaranthus retro- flexus	53 ; 60	97,90	HS
		SOLNI	Solanum nigrum	20 ; 34; 53;60	91,60	S
		BRSNW	Brassica napus	20;34;25;42;29; 39;33;43	91,30	S
		ECHCG	Echinochloa crus- galli	25;27;28;31;33;36;41;42;43;45;53;59;60	80,10	MS
		CHEAL	Chenopodium album	20;25;27;28;30; 32;33;36;41;42; 43;45;53;54;59; 60	96,90	HS
		POLCO	Polygonum convolvulus	27;25;36;41;45 ;59	90,20	S
		POLPE	Polygonum macu- losa	28;31;36;42;53;58	91,20	S
		VIOAR	Viola arvensis	27;25;29;30;39; 41;42;45;54	89,00	S
		SPRAR	Spergula arvensis	27;41	97,00	HS

	GERPU	Geranium-pusillum	20;27;34;45	92,80	S
	EROCI	Erodium-cicutarium	19;27;33;45	100,00	HS
	MATIN	Matricaria-inodora	15;22;25;28;31 36;42	97,30	HS
	STEME	Stellara-media	22;25;29;30;33; 36;39;43;54	91,30	S
	GALAP	Galium-aporine	29;30;39;54	87,50	S
	VERPU	Veronica-pulvi	25;42	97,50	HS
	CAPBP	Capsella-bursa- pastoris	29;30;33;39;43;54	95,40	S
	THALR	Thlapsi-arvense	28;30;36;54	98,10	HS
	GASPA	Galinsoga-parviflo- ra	42;36;52;59	100,00	HS
	VIOTR	Viola-tricolora	31;42;44;61	81,00	MS
	CONAR	Convolvulus-arven- sis	31;36;42;59	97,70	HS
	PAPRH	Papaver-rhoeas	44;61	57,50	T

Conclusions

Based on the data obtained from efficacy trials for product AG-F8-250CS (Racer 250 CS) applied at target dose rate: 2,0 l/ha , weeds can be classified:

Table 3.2 – 15: Average susceptibility classification of weed plants in potato (SOLTU) vs susceptibility classification in two assessment intervals, for product AG-F8-250CS (Racer 250 CS) applied at target dose rate: 2,0 l/ha

classification assessments	-19-53 DAA (11 trials)	-32-60 DAA (11 trials)	average efficacy across all trials
HS	BRSNW, EROCI, MATIN, STEME, THLAR, GASPA, CONAR, (SPRAR, PARPH, VERPU)	BRSNW, EROCI, MATIN, CAPBP, THLAR, GASPA, VIOTR, CONAR, (AMARE, VERPU)	BRSNW, EROCI, MATIN, THLAR, GASPA, CONAR, (VER- PU)
S	SOLNI, CHEAL, POLCO, POLPE, GERPU, GALAP, CAPBP, VIOTR, (AMARE)	SOLNI, CHEAL, POLCO, (GERPU, STEME, GALAP, (SPRAR)	SOLNI, CHEAL, POLCO, GERPU, STEME, GALAP, CAPBP, VIOTR, (AMARE, PAPRH, SPRAR)
MS	VIOAR, ECHCG	ECHCG, VIOAR, (PAPRH), POLPE	ECHCG, POLPE, VIOAR
MT	—	—	—
T	—	—	—

Weed plants marked in red: AMARE, PAPRH, SPRAR, VERPU — not sufficient data obtained to be classified and recommended.

Table 3.2 -15: Susceptibility classification of weed plants in potato (SOLTU) in two assessment intervals, for product AG-F8-250CS (Racer 250 CS) applied at the target dose rate of 2,0 l/ha

Classification	19-53 DAA (11 trials)	32-60 DAA (11 trials)
HS	BRSNW, CAPBP, CONAR, GASPA, EROCI, MATIN, SPRAR, STEME, THLAR, VERPU, VIOTR	AMARE, BRSNW, CAPBP, CONAR, GASPA, EROCI, MATIN, STEME, THLAR, VERPU, VI- OTR
S	CHEAL, GALAP, GERPU, POLPE, POLCO, SOLNI,	CHEAL, GALAP, GERPU, POLCO, SOLNI, SPRAR,
MS	ECHCG, PAPRH, VIOAR,	ECHCG, PAPRH, POLPE, VIOAR,
MT	no weeds classified as moderately tolerant	no weeds classified as moderately tolerant
T	no weeds classified as tolerant	no weeds classified as tolerant

* weed codes in italics: AMARE, CONAR, EROCI, PAPRH, SPRAR, VERPU, VIOTR— not sufficient data obtained for the species to be classified (appeared in single trials only).

Table 3.2 -15 a: Susceptibility classification of weeds in potato (SOLTU) for AG-F8-250CS (Racer 250 CS) at 2,0 l/ha after excluding the species recorded from single trials.

Classification	19-53 DAA (11 trials)	32-60 DAA (11 trials)
HS	BRSNW (4)*, CAPBP (3), GASPA (2), MATIN (4), STEME (4), THLAR (2),	BRSNW (4), CAPBP (3), GASPA (2), MATIN (4), STEME (4), THLAR (2),
S	CHEAL (9), GALAP (2), GERPU (2), POLPE (3)**, POLCO (4), SOLNI (2),	CHEAL (9), GALAP (2), GERPU (2), POLCO (4), SOLNI (2),
MS	ECHCG (8), VIOAR (5),	ECHCG (8), POLPE (3)**, VIOAR (5),
MT	no weeds classified as moderately tolerant	no weeds classified as moderately tolerant
T	no weeds classified as tolerant	no weeds classified as tolerant

* the number of trials

**POLPE cannot be included in the product label

Comments of zRMS on efficacy and weed classification:

Weeds that had occurred in a single trial cannot be classified and listed in the product label as susceptible targets, and species of economical importance cannot be reliably classified if recorded from less than 4 trials. The applicant has not provided justification for submitting the limited set of trials for a number of important weeds. However, the Table 3.2-15 a includes also those species, which appeared in at least two, but still less than four trials (CAPBP, GASPA, SOLNI, THLAR and POLPE). As CAPBP, GASPA, SOLNI and THLAR have been listed in the label of the preceding formulation (RACER 250 EC) and classified as vulnerable, they are considered as previously evaluated and may be included in the label of the test item. Only POLPE, though important in potato cultures, did not appear in the label of preceding formulation and has occurred in only 3 trials in the present submission. POLPE cannot be classified.

Product AG-F8-250 CS (Racer 250 CS) should be used once in a season at spring, applied directly after sowing. Recommended water volume: 200- 250 l/ha .

~~Use of AG-F8-250 CS (Racer 250 CS) according to the proposed GAP does not represent a hazard to rotational crops and does not justify a specific labeling.~~

Comments of zRMS:

As explained by the applicant in 3.5.1 (the present document): “Detailed information had been submitted at first registration of flurochloridone product Racer 250 EC”. It is therefore assumed that the data on possible effect on rotational crops was presented and had been evaluated elsewhere, making the last sentence above out of place.

Minor use

n.a.

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

No yield data from efficacy trials have been submitted. The effect of the test product on yield of the SOLTU is discussed further in the “Adverse effects...” (chapter 3.4), based on eight selectivity trials.

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

Racer 25CS is intended to be applied once per growth season at the maximum dose rate of 2.0 L/ha (500 g flurochloridone/ha) for weed control ~~on~~ in potato. Resistance risk analysis for the active substance was conducted in accordance to EPPO guideline PP 1/213(3).

Mode of action

Flurochloridone is a selective herbicide belonging to the HRAC F1 group. It belongs to the pyrrolidone chemical group. This substance is not systemic since its migration in the plant is low. It inhibits the phytoene desaturase, PDS enzyme, and thus the synthesis of carotenoids, which leads to the loss of the protective pigments of the chlorophyll molecules. Flurochloridone penetrates in the plant by the underground plant parts between germination and seedling emergence.

Resistance mechanism

Resistance mechanisms are unknown. Evidence of resistance: According to The International Survey of Herbicide Resistant Weeds no resistance cases are known for Flurochloridone. However, 3 studies showed resistances cases of *Raphanus raphanistrum* and *Sisymbrium orientale* against diflufenican, another herbicide of the HRAC F1 Group.

Cross-resistance

No cases of cross-resistance between flurochloridone and other herbicides were found in the literature.

Sensitivity data

No studies on baseline sensitivity are available for flurochloridone.

Use pattern

AG-F8-250CS (Racer 250 CS) is intended to be applied once per growth season at the maximum dose rate of 2.0 L/ha (500 g flurochloridone/ha) for weed control in potato.

Resistance risk assessment of unrestricted use pattern

Inherent risk of resistance development related to the active substance: Medium risk to develop resistance to herbicides is defined for weeds for which one mode of action is reported and the frequency of reported resistance is low. For weeds species for which no cases of resistance are reported the risk to develop resistance is classified as low. As the mode of action of flurochloridone is targeted on a specific metabolic mechanism, the inhibition of carotenoid biosynthesis at the phytoene desaturase step, it can be considered that the risk of resistance inherent to the active substance flurochloridone is medium to low.

Inherent risk of resistance development of the target weeds

Flurochloridone has a broad spectrum against a few grass weeds and many broad-leaved weeds. Resistant cases have already been observed against other MoA groups of herbicides (especially herbicides belonging to the C1/5 Group) on several targeted weeds such as CHEAL, SOLNI for example. As a lot of weeds have inherent abilities to develop resistance mechanisms, the overall risk of resistance development inherent to target weeds is thus considered as high. <http://www.weedscience.com/summary/home.aspx>, accessed on 27/02/2013.

Evaluation of the agronomic risk of resistance development

As only 1 application maximum per season is requested for weed control, as there are only 1 intended use: SOLTU and as AG-F8-250CS (Racer 250 CS) will be likely to probably be used in programme with 2 or 3 other herbicides with different modes of action for weed control, it can be considered that the risk of resistance development related to the agronomic practice is low.

Conclusion on the risk of resistance development related to the use of AG-F8-250CS (Racer 250 CS) for weed control

Considering the mode of action of flurochloridone, it is likely that a weed develops a resistance to flurochloridone as it could be on fliflufenican. However, no resistance cases are known for flurochloridone despite the fact that diflufenican and flurochloridone were both discovered during the 1980's. Moreover, the risk of resistance development related to the agronomic practice is low (1 application per year on only 1 use and likely use of AG-F8-250CS (Racer 250 CS) likely to be used in programme with other herbicides). It is thus concluded that the risk of resistance related to the use of AG-F8-250CS (Racer 250 CS) for weed control in potato can be considered as low.

Resistance Management strategies

As the overall risk of resistance is medium and as only 1 application per season is requested for weed control.

Summary and conclusion

Considering the mode of action of flurochloridone, it is likely that a weed develops a resistance to flurochloridone as it could be on flufenican. However, no resistance cases are known for flurochloridone despite the fact that diflufenican and flurochloridone were both discovered during the 1980's. Moreover, the risk of resistance development related to the agronomic practice is low (1 application per year on only 1 use and AG-F8-250CS (Racer 250 CS) is likely to be used in programme with other herbicides). It is thus concluded that the overall risk of resistance related to the use of AG-F8-250CS (Racer 250 CS) for weed control in potato can be considered as medium.

Comments of zRMS:

To the opinion of zRMS, even taken the absence of resistance reported to flurochloridone *per se*, standard resistance management strategy must be incorporated in the product label, in order to constantly stimulate the end user's awareness of the resistance issue and of the risk involved. As explained by the applicant, the active of the test item is not the only herbicide in the market belonging to the MoA group no 12, therefore the limited number of applications per growth season alone do not warrant the limited exposure of weeds to this mode of action.

The applicant has proposed some resistance management strategies to be placed in the product label, but had provided them exclusively within the label project, *i.e.* only in Polish wording.

Some of these strategies are:

“Observe the recommended dose rate of the product and the recommended application time indicated in the label, in order to achieve maximum efficacy of weed control resulting from the application on susceptible developmental stages of weeds,

Always apply Racer 250 CS on moist soil, to provide optimum migration of the active substance in soil and its translocation to germinating weeds, thus avoiding ineffective weed control,

Use the product in rotation with herbicides showing different mode of action, classified in other MoA groups than flurochloridone,

Use the product only once pre growth season,

Integrate crop rotation, mechanical weeding and other non-chemical methods with the chemical control in one cohesive system of weed management.”

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted

Eight selectivity trials were conducted in Poland in 2018 (4) and 2018(4). Phytotoxicity assessments were also done on all efficacy trials presented in this dossier.

Table 3.4-1: Presentation of selectivity trials

Crop*	Country	Type of trial**	Number of trials	Years	GEP	Comments (any other relevant information)
			Central zone			
SOLTU/potato	Poland	S + Y	8	2018 - 2019	GEP	
TOTAL	-	-	8	-	-	

* According to the GAP table

** S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process (TP: Physical transformation, TF: transformation involving microbial fermentation), P = trial with assessment of impact on propagation

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

Crop	Refer- ence standard	Coun- try(ies) where the product is registered (1)	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered applica- tion rate ⁽³⁾	Applica- tion rate in trials (per treatment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concen- tration of a.s.			
SOL- TU / potato	Racer 250 EC	PL	R-8/2003	Flurochlo- ridone	EC	250 g/L	2,0 – 3,0 l/ha	2,0 – 3,0 l/ha 2,0 and 4,0 L/ha	

(1) only on use(s) applied for (with the test product); (2) e.g. WP (wetttable powder), EC (emulsifiable concentrate), etc.; (3) Dose / dose range authorized in the country; (4) Other relevant information (e.g. uses, number of applications, spray volume, method of application...)

Table 3.4-3: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135(4), EPPO PP 1/152(4), EPPO PP 1/181(4)
	Specific guidelines	EPPO PP 1/51(3) followed only in PL19HSSOLTU032C and PL19HSSOLTU032D
Experimental design	Plot design	RCBD
	Plot size	22,4 20,0-27,0 m ²
	Number of replications	4
Crop	Trials per crop	SOLTU (8)
	Varieties per crop	Denar, Tomensa, Vineta, Lilly, KWS Leonata, Lady Claire, Orlena, Taurus
	Sowing period	2018-04-20, 2018-04-28, 2018-05-02, 2018-05-17, 2019-04-10, 2019-04-24, 2019-05-04, 2019-05-24 2018-05-30 2018-05-08 2018-05-03 2018-05-07 15/04/2019 10/05/2019 06/06/2019 14/05/2019
Application	Crop stage (BBCH)* at application	BBCH 00-09 BBCH 00-07
	Timing Pest stage at application (1)	Pre-emergence /weed free
	Number of applications Intervals between applications	1 n.a.
	Spray volumes	200-250 L/ha 200 L/ ha (2 trials); 250 L/ha (6 trials)
Assessment	Assessment types (number of trials)	Visual estimation of phytotoxicity according to percentage scale 0-100% Vigor of plants according to scale 0-10 Emergence (szt/m2, %) length of shoots (cm) Yield (kg/plot, t/ha) (8) Calibration (4) (5) Starch content (3)
	Assessment dates	3-4 assessments in the range of 7-70 DAA 7-86 DAA, at BBCH 12-66
Other relevant information	e.g. Soil type, pH	Humus earth Humus earth, sandy clay, fine loam, silt loam, loam, clayey sand pH: 5,5 – 6,6
	e.g. Field / Greenhouse...	Field trials

* BBCH for weeds, pre-emergence, preventive / curative application, in

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

The phytotoxicity of product AG-F8-250CS (Racer 250 CS) was evaluated in 11 efficacy trials on SOLTU and in 8 selectivity trials. AG-F8-250CS (Racer 250 CS) was applied at the maximum rate (2N): of 4,0 L/ha. Phytotoxicity symptoms can be observed shortly after application but these symptoms are slight and transient, and without any influence on the yield.

Tested varieties in selectivity trials: Denar, Tomensa, Vineta, Lilly (2018), KWS Leonata, Lady Claire, Orlena, Taurus (2019). Tested varieties in efficacy trials: Gala, Soraya, Zuzanna (2018), Innovator, Denar, Tomensa, Albatros, Lilly, Toskana, Natasha (2019).

Materials and methods

Totally 8 reports (S+Y) of selectivity trials are presented in the dossier, showing the results of the research into product selectivity carried out in 2018 and 2019 in SOLTU in Poland. The list of these reports is contained in Appendix 1.

Site

Trials were conducted in different regions of the Poland where SOLTU is grown commercially. Trials was established on a set of complete randomized blocks in 4 replications.

Testing units

The field selectivity trials of the AG-F8-250CS (Racer 250 CS) were carried out by the following units:

- 1) Fertico Sp. z o.o.
- 2) Agreco Sp z o.o. ,

The testing units have been mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized.

Experimental details

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:

1. PP 1/135 (3) Phytotoxicity assessment;
2. PP 1/152 (4) Design and analysis of efficacy evaluation trials;
3. PP 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice.
4. PP 1/51(3) Weeds in potato.

Assessment methods

Statistical Analysis

Data were analysed using a two-way analysis of variance (ANOVA). The probability of non-significant differences occurring between treatment means is calculated as the F probability value (Prob(F)). Student-Newman-Keuls test was then applied to separate any treatment differences that may be implied by the ANOVA TEST (Prob(F)<0.05) and these are indicated by the LSD-value and by a letter-test. Statistical analysis was carried out with the use of statistic pack of ARM Research Manager 9 Software (Gylling Data Management).

Assessment of phytotoxicity

Phytotoxicity was assessed by a visual estimation of an intensity of deformation, growth reduction and plant vigour found on overall areas of treated plots, with references to untreated plots. A percentage scale from “0” to “100” was used for the phytotoxicity assessment, in which “0” meant no damage whereas “100” meant a total damage found.

VIGOR - Vigor of plants according to scale 0-10, where: 0 –plant without vigour ; 100 –full vigour
Influence on yield was assessed by evaluation of kg/plot and t/ha. Quality assessment included moisture content (%) and oil content (%).

EMEDEL - emergence delay emergence (plants/m², %)

LENGTH - length of shoots (cm)

PHYDFL - flowering delay (%/plot)

Harvest

Tuber yield from the plot was harvested

YIELD: kg/plot ; t/ha

STACON: starch content (3 trials : PL19HSSOLTU032A/B/D)

TUBHAR: harvested tubers classified within 3 classes, depending on it size:

< 35 mm 35-50 mm 50-65 mm > 65 mm

(5 trials: PL18HSSOLTU071A/B/C/D and PL19HSSOLTU032C)

Applications methods and rates

The application were conducted with Backpack sprayer/ compressed air plot sprayer and Sprayer with a boom UP-02. The tested product was applied according to the treatment list :

Name	Rate (kg, l/ha)	Other rate (g a.s./ha)	Appl Code	Growth stage (BBCH)
Untreated Check				
AG-F8-250CS (RACER 250 CS)	2	500	A	BBCH 00-09
AG-F8-250CS (RACER 250 CS)	4	1000	A	BBCH 00-09
RACER 250 EC	2	500	A	BBCH 00-09
RACER 250 EC	4	1000	A	BBCH 00-09

Table 3.4-4: Phytotoxicity of product

Number of trials with...		Selectivity trials (20 trials)			Efficacy trials (11 trials)		
		AG-F8-250CS (Racer 250 CS)		Racer 250 EC	AG-F8-250CS (Racer 250 CS)		Racer 250 EC
		N	2N	N	2N	N	N
Maximum of phytotoxicity recorded during the trials	≥0% to 5%	3	3	3	1	4	4
	>5% to 10%	0	2	1	2	1	1
	>10% to 15%	0	0	0	0	0	1
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	≥0% to 5%	0	1	0	0	0	0
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Phytotoxic effects in efficacy trials

11 efficacy field trials were conducted in 2018-2019 . Symptoms of phytotoxicity like: leaf bleaching (PHYBLE) were observed on 2 of 11 trials (PL19HESOLTU031E and F), varieties: Gala and Lilly and general phytotoxicity (PHYGEN) on 5 of 11 trials (PL19HESOLTU031A, PL19HESOLTU031C; PL19HSSOLTU032A; PL18HESOLTU070A, PL18HESOLTU070B and PL18HESOLTU070D), varieties: KWS Leonata, Innovator, Tomensa, Gala, Soraya and Zuzanna.

General phytotoxicity (PHYGEN) of tested product : AG-F8-250CS (Racer 250 CS) applied at 1N dose rate – 2,0 l/ha, higher than 5% (5,3%) was observed on one trial: PL18HESOLTU070D, variety: Zuzanna at DAA 9 – 5,3% ; DAA 20 – 3,8 % . In the same trial similar PHYGEN symptoms were

observed for the reference Racer 250 EC (2,0 L/ha): 11,0% at 9 DAA and 7,3% at 20 DAA.
No phytotoxic effects were observed at last assessment on any of efficacy trials.

Phytotoxic effects on selectivity trials.

8 selectivity trials were conducted in 2018 – 2019. Symptoms of phytotoxicity were observed on 5 of 8 trials. General phytotoxicity (PHYGEN) lower/equal than 5% observed on 3 of 8 trials, on both treatments: test item AG-F8-250CS (Racer 250 CS) (1N) and reference product Racer 250 EC (1N). in 2 trials with both AG-F8-250CS (Racer 250 CS) and the reference Racer 250 EC at 1N (2,0 L/ha) dose rate.

In 1 trial: PL19HSSOLTU032B (var. Lady Claire) leaf chlorosis (PHYCHL) on level higher than 5% were observed on treatment of reference product : Racer 250 EC applied at target dose rate: 2,0 l/ha : DAA 21 – 6,5% (PHYCHL) and 1,5 % (PHYBLE) (3,5% and 0,5% respectively in the AG-F8-250CS treated plots, the same dose rate and assessment date).

Phytotoxic symptoms (PHYGEN) lower/equal than \leq 5% were observed in treatments with the test item AG-F8-250CS (Racer 250 CS) (2N) in 2 of 8 trials, and in treatments with the reference product Racer 250 EC (2N) - in only one trial.

In 2 of 8 trials phytotoxic effects like chlorosis, necrosis and stunting, in the range of 5-10% , were observed on 2N treatment with the test item AG-F8-250CS (Racer 250 CS). and reference product Racer 250 EC.

Only in one trial phytotoxic symptoms were observed on the last assessment (5%) (3,5% 35 DAA, chloroses): PL19HSSOLTU032C (var Lady Claire) on treatment of test time with the test item AG-F8-250CS (Racer 250 CS) applied at 2N dose rate.

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

8 selectivity trials (YIELD) were conducted in 2018-2019 in Poland (NE). Test product AG-F8-250CS (Racer 250 CS) were applied at dose rates: 1N – 2,0 l/ha and 2N – 4,0 l/ha used reference product: Racer 250 EC were also applied at 1N dose rate : 2,0 l/ha and 2 N dose rate : 4,0 l/ha.

Phytotoxicity symptoms (PHYSTU, PHYBLE, PHYCHL, PHYNLT , PHYNLM) were observed on 5 of 8 trials for both : test product and reference applied at 1N dose rate and 2N dose rate. There were no statistically significant differences in yield and its parameters between test product AG-F8-250CS (Racer 250 CS) and reference product Racer 250 EC.

Table 3.4-5: Relationship between phytotoxicity and yield.

Test report	Variety	Maximum phyto. at 1N rate (%) (DAA)		Maximum phyto. at 2N (or other) rate (%) (DAA)		Yield in the untreated control Absolute figures (unit)	Yield at 1N as % of untreated		Yield at 2N (or other) rate as % of untreated	
		Test product	Standard 1	Test product	Standard 1		Test product	Standard 1	Test product	Standard 1
n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a	n.a

Comments of zRMS:

As the phytotoxicity symptoms were infrequent in efficacy and selectivity trials and no significant negative effect on yield quantity has been reported from any of the 6 selectivity trials in which the yield was tested, the applicant has left the Table 3.4-5 blank, which is acceptable in light of the relevant EPPO guidance. For the sake of completeness the zRMS has presented the mean yield, in kg per plot, from the selectivity trials, in the table below.

Treatment	Dose rate L/ha	Yield kg/plot	min	max
UNCK handweeded	0,0	54,8	28,2	102,4
AGF-F8-250 CS	2,0	55,1	29,0	103,5
AGF-F8-250 CS	4,0	55,4	26,6	104,7

RACER 250 EC	2,0	55,4	31,2	105,2
RACER 250 EC	4,0	55,2	28,2	107,5

The yield in t/ha is shown in the following Table 3.4.3-1, amended slightly by zRMS in order to make it legible.

In all 8 selectivity trials test item AG-F8-250CS (Racer 250 CS) applied at proposed label dose rate: 2,0 l/ha (1N) and 4,0 l/ha (2N), had no negative effect on yield of potato (SOLTU) under weed-free conditions.

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

8 selectivity (Yield) trials performed in Poland (NE) between 2018-2019. Test item AG-F8-250CS (Racer 250 CS) was applied at target dose rate : 2,0 l/ha (1N) and double dose rate : 4,0 l/ha (2N) also reference Racer 250 EC was applied accordingly : at 1N and 2N of the target dose rate. Trials were harvested, yield estimated and yield parameters determined. (K.C.P 6.4)

Table 3.4.3 -1: Yield in t/ha /Yield parameters:

Parameter	No. of trials	Untreated control			Rating unit	Yield of tubers in particular size class % Untreated control					
						AG-F8-250CS 2,0 l/ha (1N)			Racer 250 EC 2,0 l/ha (2N)		
		Mean	Min.	Max.		Mean	Min.	Max.	Mean	Min.	Max.
harvestable tuber class < 35 mm	5	3,22	1,09	4,88	kg/plot	2,97	1,35	4,30	3,11	0,95	4,48
harvestable tuber class 35 - 50 mm	5	17,34	7,49	28,95	kg/plot	17,41	7,45	27,05	17,37	8,05	29,38
harvestable tuber class 50 - 60 65 mm	5	24,19	6,48	47,01	kg/plot	24,83	7,38	49,52	24,80	7,18	47,26
harvestable tuber class > 65 mm	5	11,68	4,68	21,55	kg/plot	11,54	3,85	22,67	11,74	2,90	24,74
starch content and yield											
STACON	3	17,11	15,45	19,83	%	17,61	15,78	20,90	16,99	15,18	19,78
Yield	8	41,80	31,33	51,20	t/ha	42,04	32,25	51,80	42,04	31,19	52,60

8 selectivity trials conducted between 2018-2019 in Poland revealed no negative effect on yield and its parameters.

Comments of zRMS:

The phytotoxicity of AG-F8-250CS was monitored in 11 efficacy trials as symptoms on plants and was separately tested in 8 selectivity trials, of which six tested yield, five of them tested harvestable yield and three tested starch content in tubers.

Phytotoxicity was infrequent in efficacy and selectivity trials, and none of the phytotoxicity symptoms reported from the proper selectivity trials (mostly bleaching and chloroses) affected yield quantity or quality.

In one selectivity trial (PL19HSSOLTU032C) the growth stunting was observed on 28 DAA, with the same intensity caused by the test item and the reference, and with 5% intensity at 1N dose rate and 10% - at 2N dose. On the last assessment available for inspection the intensity of the symptom was 5% in the plots treated with either of the two products at 2N, and 0% in the plots treated with the target 1N dose of 2,0 L/ha.

It has been concluded that no significant negative effect on yield and its parameters should be expected after application of the test item, compared to the former formulation used as standard reference: Racer 250 EC.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Lack of additional tests in this range. Active substances comprising in this product has been applied for many years, not only in Poland but also in the other countries of Europe. Detailed information had been submitted at first registration of flurochloridone product Racer 250 EC

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

No specific studies/trials conducted.

Summary and conclusion

The phytotoxicity of product AG-F8-250CS (Racer 250 CS) was evaluated in 11 efficacy trials on SOLTU and 8 selectivity trials. AG-F8-250CS (Racer 250 CS) was applied at the maximum rate of 4,0 L/ha (2N). Phytotoxicity symptoms can be observed shortly after application but these symptoms are slight and transient, and without any influence on the yield. Tested varieties in selectivity trials: Denar, Tomensa, Vineta, Lilly (2018), KWS Leonata, Lady Claire, Orlena, Taurus (2019). Tested varieties in efficacy trials: Gala, Soraya, Zuzanna (2018), Innovator, Denar, Tomensa, Alba-tros, Lilly, Toskana, Natasha (2019). Phytotoxicity symptoms (PHYSTU, PHYBLE, PHYCHL, PHYNLT, PHYNLM) were observed in 5 of 8 trials wither for the test item and the reference product applied at 1N dose rate and 2N dose rate.

There were no statistically significant differences in yield and its parameters between test product AG-F8-250CS (Racer 250 CS) and reference product Racer 250 EC.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Lack of additional tests in this range. Active substances comprising in this product has been applied for many years, not only in Poland but also in the other countries of Europe. Detailed information had been submitted at first registration of flurochloridone product Racer 250 EC.

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

Tank cleaning

Not applicable.

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

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

Compatibility with current management practices including IPM

Not applicable

3.6 Other/special studies

Not performed.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Test facility	Address	Certificate (Yes or No)
Agreco Sp z o.o.	al. Lipowa 21, lok. 1, 53-124 Wrocław, Oddział: Gać 64A, 55-200 Oława, Poland	Y
Fertico Sp z o.o.	Goliany 43, 05-620 Błędów, Poland	Y
Uniwersytet Przyrodniczy in Augusta Cieszkowskiego Centrum Badawczo - Edukacyjne Gorzyń	ul. Wojska Polskiego 28; 60-637 Poznań, Poland	Y
Eurofins Agrosience Services Sp. z o.o.	ul. Parkowa 6 ; 64-530 Kaźmierz, Poland	Y
Staphyt Sp z o.o.	ul. Ziebicka 2, 60-164 Poznań , Poland	Y
Agreco Sp z o.o.	al. Lipowa 21, lok. 1, 53-124 Wrocław, Oddział: Gać 64A, 55-200 Oława, Poland	Y

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6	Daniel Słomka	2018	Określenie skuteczności działania preparatu Racer 25 CS (AG-F8-250 CS; flurochloridon 250 g/l) zastosowanego przedwschodowo w zwalczaniu chwastów dwuliściennych w uprawie ziemniaka. Polska, 2018. Efficacy evaluation of a pre-emergence application of Racer 25 CS (AG-F8-250 CS; flurochloridon 250 g/l) against broad-leaved weeds in potato. Poland, 2018. GEP Not Published Trial sponsor code: PL18HESOLTU070A Final report nr: S18-02668-01	N	ADAMA Polska
KCP 6	Monika Brodała-Jabłońska	2018	Określenie skuteczności działania preparatu Racer 25 CS (AG-F8-250 CS; flurochloridon 250 g/l) zastosowanego przedwschodowo w zwalczaniu chwastów dwuliściennych w uprawie ziemniaka. Polska, 2018. Efficacy evaluation of a pre-emergence application of Racer 25 CS (AG-F8-250 CS; flurochloridon 250 g/l) against broad-leaved weeds in potato. Poland, 2018. GEP Not published Trial sponsor code: PL18HESOLTU070B Final report no S18-02668-02	N	ADAMA Polska
KCP 6	dr inż. Agnieszka Kukuła, PhD	2018	Ocena skuteczności preparatu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka (The evaluation of efficacy of AG-F8-250 CS for the control of weeds on potato) GEP Not published sponsor's code: PL18HESOLTU070D final report nr: 18ADA0409-2	N	ADAMA Polska
KCP 6	dr inż. Agnieszka Kukuła, PhD	2019	Ocena skuteczności i selektywności preparatu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka (The evaluation of efficacy and selectivity of AG-F8-250 CS for the control of weeds on potato) “Efficacy and selectivity of AG-F8-250 CS in potato in Poland in 2019” GEP Not published Sponsor's code: PL19HESOLTU031A Final report nr: 19ADA0581-1	N	ADAMA Polska
KCP 6	Mgr inż. Adam	2019	Skuteczność preparatu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka. Polska 2019	N	ADAMA Polska

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Szemendera		Efficacy of AG-F8-250 CS in control of weeds in potato, Poland 2019 GEP Not published Sponsor's code: PL19HESOLTU031B Final report nr: 212_01_F19_362		ska
KCP 6	Mgr inż. Adam Szemendera	2019	Skuteczność preparatu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka, Polska 2019 Efficacy of AG-F8-250 CS in control of weeds in potato, Poland 2019 GEP Not published Sponsor's code: PL19HESOLTU031C Final report nr: 1_01_F19_01	N	ADAMA Polska
KCP 6	Mgr inż. Adam Szemendera	2019	Skuteczność preparatu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka, Polska 2019 Efficacy of AG-F8-250 CS in control of weeds in potato, Poland 2019 GEP Not published Sponsor's code: PL19HESOLTU031D Final report nr: 1_02_F19_02	N	ADAMA Polska
KCP 6	Adam Pawlak	2019	Skuteczność i selektywność AG-F8-250 CS stosowanego przeciwko chwastom w ziemniakach, Polska 2019 Efficacy and selectivity of AG-F8-250 CS in potato in Poland 2019. GEP Not published Sponsor's code: PL19HESOLTU031E Finl report nr: APK-19-39012-PL01	N	ADAMA Polska
KCP 6	Adam Pawlak	2019	Skuteczność i selektywność AG-F8-250 CS stosowanego przeciwko chwastom w ziemniakach, Polska 2019 Efficacy and selectivity of AG-F8-250 CS in potato in Poland 2019. GEP Not published Sponsor' code: PL19HESOLTU031F Final report nr: APK-19-39012-PL02	N	ADAMA Polska
KCP 6	Beata Szymańska	2019	Badanie skuteczności produktu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka Efficacy of product AG-F8-250 CS against herbs in potatoes cultivation. GEP Not published Sponsor's code: PL19HESOLTU031G Trial code: AF/19/Z/13/Gr/031G	N	ADAMA Polska

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6	Beata Szymańska	2019	Badanie skuteczności produktu AG-F8-250 CS w zwalczaniu chwastów w uprawie ziemniaka Efficacy of product AG-F8-250 CS against herbs in potatoes GEP Not published Sponsor's code: PL19HESOLTU031H Trial code: AF/19/Z/13/ZŁ/031H	N	ADAMA Polska
KCP 6.4	Mgr Krzysztof Rusek	2018	Selektywność preparatu AG-F8-250 CS stosowanego w terminie zwalczania chwastów w uprawie ziemniaka, Polska 2018 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2018 GEP Not published Sponsor' code: PL18HSSOLTU071A Final report nr: 123_01_F18_256	N	ADAMA Polska
KCP 6.4	Mgr Krzysztof Rusek	2018	Selektywność preparatu AG-F8-250 CS stosowanego w terminie zwalczania chwastów w uprawie ziemniaka, Polska 2018 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2018 GEP Not published Sponsor' code: PL18HSSOLTU071B Final report nr: 123_02_F18_257	N	ADAMA Polska
KCP 6.4	Mgr Krzysztof Rusek	2018	Selektywność preparatu AG-F8-250 CS stosowanego w terminie zwalczania chwastów w uprawie ziemniaka, Polska 2018 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2018 GEP Not published Sponsor' code: PL18HSSOLTU071C Final report nr: 123_03_F18_258	N	ADAMA Polska
KCP 6.4	Mgr Krzysztof Rusek	2018	Selektywność preparatu AG-F8-250 CS stosowanego w terminie zwalczania chwastów w uprawie ziemniaka, Polska 2018 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2018 GEP Not published Sponsor' code: PL18HSSOLTU071D Final report nr: 123_03_F18_259	N	ADAMA Polska
KCP 6.4	dr inż. Agnieszka	2019	Ocena selektywności preparatu AG-F8-250 CS w uprawie ziemniaka	N	ADAMA Polska

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Kukuła, PhD		(The evaluation of selectivity of AG-F8-250 CS on potato) “Selectivity of AG-F8-250 CS on potato in Poland in 2019” GEP Not published Sponsor’ code: PL19HSSOLTU032A Final report nr: 19ADA0580-1		ska
KCP 6.4	dr inż. Agnieszka Kukuła, PhD	2019	Ocena selektywności preparatu AG-F8-250 CS w uprawie ziemniaka (The evaluation of selectivity of AG-F8-250 CS on potato) “Selectivity of AG-F8-250 CS on potato in Poland in 2019” GEP Not published Sponsor’ code: PL19HSSOLTU032B Final report nr: 19ADA0580-2	N	ADAMA Polska
KCP 6.4	Mgr inż. Adam Szemendera	2019	Selektywność preparatu AG-F8-250 CS stosowanego w zwalczaniu chwastów w uprawie ziemniaka, Polska 2019 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2019 GEP Not published Sponsor’ code: PL19HSSOLTU032C Final report nr: 2_01_F19_03	N	ADAMA Polska
KCP 6.4	Mgr inż. Adam Szemendera	2019	Selektywność preparatu AG-F8-250 CS stosowanego w zwalczaniu chwastów w uprawie ziemniaka, Polska 2019 Selectivity of AG-F8-250 CS in control of weeds in potato, Poland 2019 GEP Not published Sponsor’ code: PL19HSSOLTU032D Final report nr: 2_02_F19_04	N	ADAMA Polska

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-