

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

Product code: MEZI 100 SC  
Product name(s): **Rumezo Twist 100 SC/Malton Twist 100 SC**  
Chemical active substance:  
mesotrione 100 g/L

Central zone:  
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Innvigo Sp. z o.o.  
Submission date: December 2023, **October 2024**  
zRMS Assessment: 24/07/2024  
**Following commenting period: 21/10/2024**

## Version history

When	What
July 2024	zRMS assessment
October 2024	Following commenting period
October 2024	Applicant update

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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)**

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. The parts of the text amended or added by the zRMS evaluator are highlighted in grey and the parts struck off are <del>visibly marked with the grey font.</del>
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#### **3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)**

##### **Abstract**

The overall assessment was performed according to the uniform principles. ZRMS considers that the data provided support the following use: 1 presented in the GAP table.

During the evaluation, the unprotected efficacy data performed for Callisto 100 SC was also used for MEZI 100 SC.

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g saf- ener/synergist pe ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg 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	Maize (ZEAMX)	F	Mono and dicotsweeds	Spray, me- dium sprayer	Spring BBCH 14-15	a)1 b)1	n/a	a) 1.0 L/ha b) 1.0 L/ha	a) 100 g a.s./ha b) 100 g a.s./ha	200-300	n/a	
2													
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
(c) g/kg or g/l

(d) Select relevant  
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

<b>Remarks columns:</b>	1	Numeration necessary to allow references	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.
	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	Minimum interval (in days) between applications of the same product
	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	For specific uses other specifications might be possible, e.g.: g/m <sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

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

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

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

## 3.2 Efficacy data (KCP 6)

### Introduction

This document summarizes the information related to the efficacy of the product MEZI 100 SC containing active substance ~~mesotrione~~ mesotrione (100 g/L), included in Annex to Commission Implementing 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 list of approved active substances.

In accordance with Article 34 of the Regulation (EC) No 1107/2009 of the European Parliament and of the Council and the guidelines of the Ministry of Agriculture and Rural Development in Poland, 3 bridging studies were submitted for the herbicide MEZI 100 SC registration in maize.

MEZI 100 SC applies in Poland for the registration in maize:  
used solo, postemergence (BBCH 14-15) at rate 1.0 L/ha once a season in maize which are corresponding to 100 g a.s./ha of mesotrione for the control of mono- and dicotyledonous weeds.

### Description of active substances

The descriptions of active substances will be provided in Section 1,2 4 to 8 and Part C.

### Mode of action

#### Active substance:

mesotrione 100 g/L

Chemical name (IUPAC): 2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione (mesotrione)

CIPAC No.: 625

CAS No.: 104206-82-8

*According to Mesotrione\_RAR\_05\_Volume\_3CA\_B-3\_2015-02-23.pdf*

Mesotrione belongs to the chemical group of the triketones (2-benzylcyclohexane-1,3-diones), which acts by blocking the function of the essential plant enzyme 4-hydroxy-phenyl-pyruvatedioxygenase (4-HPPD) in the cytosol of sensitive plants. Mesotrione is a systemic herbicide and controls most annual broadleaf and annual grass weed species in maize.

Mesotrione is taken up via roots and shoots and translocated rapidly in both the xylem and phloem into all plant parts. In sensitive plants symptoms of white chlorosis become visible within a few days after application in actively growing tissues being in the cell elongation phase. Complete death of sensitive plants may occur up to 2 weeks after application. Maize has a natural tolerance against mesotrione as it can detoxify the herbicide into inactive compounds. This detoxification is mediated by cytochrome-P450-oxygenase and is so rapid in maize that mesotrione is not translocated away from the treated zone to the point of action. Sensitive weed species cannot detoxify mesotrione in this way.

**Table 3.2-1: Details of the active substances**

Active substance	mesotrione
Concentration (Unit: g/kg or g/L...)	100 g/L
Chemical group	Triketone



Active substance	mesotrione
Mode of action	Inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase (4-HPPD).
Biological action	Mesotrione is a systemic herbicide and controls most annual broadleaf and annual grass weed species in maize. It is taken up via roots and shoots and translocated rapidly in both the xylem and phloem into all plant parts. In sensitive plants symptoms of white chlorosis become visible within a few days after application in actively growing tissues being in the cell elongation phase. Complete death of sensitive plants may occur up to 2 weeks after application.

### Description of the plant protection product

MEZI 100 SC containing 100 g/L mesotrione as the active substance is prepared for the use in agricultural practice as a herbicide in the form SC – Suspension concentrate.

MEZI 100 SC is to be applied in spring:

1.0 L/ha (100 g a.s./ha) postemergence: BBCH 14-15 in maize in Poland.

### Marketing name:

product submitted to registration under two different marketing names: Rumezo Twist 100 SC/Malton Twist 100 SC

The information concerning ingredients of product MEZI 100 SC are included in the confidential part of the registration dossier: Registration Report – Part C.

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

Uses		Member State	Requested rate(s)		Comments / Other relevant details on GAPs
Crop(s)	Target(s)		max. rate per appl	max. total rate per crop/season	
Maize	Dicots and mono weeds	PL	1.0 L/ha	1.0 L/ha	-

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

### Description of the target pests

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

EPPO code	Scientific name	Common name*
CHEAL	<i>Chenopodium album</i>	fat-hen
ECHCG	<i>Echinochloa crus-galli</i>	one-sided barnyardgrass
POLCO	<i>Fallopia convolvulus</i>	black bindweed
POLPE	<i>Polygonum persicaria</i>	lady's thumb
GAETE	<i>Galeopsis tetrahit</i>	common hemp nettle
GASPA	<i>Galinsoga parviflora</i>	gallant soldier
CAPBP	<i>Capsella bursa-pastoris</i>	shepherd's purse
SETPU	<i>Setaria pumila</i>	pale pigeongrass

\* optional

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

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Maize	PL	-	<i>Chenopodium album</i>	X	-
			<i>Echinochloa crus-galli</i>	X	-
			<i>Fallopia convolvulus</i>	X	-
			<i>Polygonum persicaria</i>	X	-
			<i>Galeopsis tetrahit</i>	X	-
			<i>Galinsoga parviflora</i>	X	-
			<i>Capsella bursa-pastoris</i>	X	-
			<i>Setaria pumila</i>	X	-

### Compliance with the Uniform Principles

The overall assessment was performed according to the uniform principles. There were no deviations from the EPPO guidelines with the trials conducted in the North-East EPPO Zone.

### Information on trials submitted (3.1 Efficacy data)

In accordance with Article 34 of the Regulation (EC) No 1107/2009 of the European Parliament and of the Council and the guidelines of the Ministry of Agriculture and Rural Development in Poland, 3 bridging studies were submitted for the herbicide MEZI 100 SC registration in maize.

The applicant submitted 3 reports (in total) showing the results in research into product efficacy carried out in 2023 in the North-East EPPO Zone in maize. List of these reports is contained in Appendix 1. Trials were carried out in one season because this herbicide contains mesotrione which is a well-known active substance that has been used for many years in agricultural practice.

**Table 3.2-5: Presentation of trials efficacy trials**

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials	GEP, non-GEP, official***	Comments (any other relevant information)
					North -East zone		
Maize	<i>Chenopodium album</i>	Poland	2023	E	3(3)	GEP	-
	TOTAL	-	2023	E	3(3)	-	-
	<i>Echinochloa crus-galli</i>	Poland	2023	E	3(3)	GEP	-
	TOTAL	-	2023	E	3(3)	-	-
	<i>Fallopia convolvulus</i>	Poland	2023	E	3(3)	GEP	-
	TOTAL	-	2023	E	3(3)	-	-
	<i>Polygonum persicaria</i>	Poland	2023	E	2(2)-	GEP	-
	TOTAL	-	2023	E	2(2)	-	-
	<i>Galeopsis tetrahit</i>	Poland	2023	E	1(1)	GEP	-
	TOTAL	-	2023	E	1(1)	-	-
	<i>Galinsoga parviflora</i>	Poland	2023	E	1(1)	GEP	-
	TOTAL	-	2023	E	1(1)	-	-

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials	GEP, non-GEP, official***	Comments (any other relevant information)
					North -East zone		
	<i>Capsella bursa-pastoris</i>	Poland	2023	E	2(2)-	GEP	-
	TOTAL	-	2023	E	2(2)-	-	-
	<i>Setaria pumila</i>	Poland	2023	E	1(1)	GEP	-
	TOTAL	-	2023	E	1(1)	-	-
	TOTAL	-		-	3(16)	-	-

\* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

\*\* P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

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

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

Crop(s)	Reference standard	Country(ies) where the product is registered <sup>(1)</sup>	Authorization number	Active substance(s)	Formulation		Registered application	Application	Remark <sup>(4)</sup>
					Type <sup>(2)</sup>	Concentration of a.s.		rate in trials (per treatment)	
maize	Callisto 100 SC	Poland	R-990/2020d	mesotrione	SC — Suspension concentrate	100 g/L	1.0 L/ha	1.0 L/ha	-

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetable 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)

Preliminary studies on product MEZI 100 SC were not carried out because this herbicide contains mesotrione which is a well-known active substance that has been used for many years in agricultural practice. According to EPPO PP1/225(2) lower doses have been tested in the efficacy studies, therefore no specific studies were conducted to fill this data point.

#### Summary and conclusions on the preliminary trials

According to EPPO PP1/225(2) lower doses have been tested in the efficacy studies, therefore no specific studies were conducted to fill this data point.

### 3.2.2 Minimum effective dose tests (KCP 6.2)

No specific studies were conducted to fill this data point.

#### Maize

In connection with registration under Article 34 of the Regulation (EC) No 1107/2009 of the European Parliament and of the Council, no minimum effective dose tests were carried out.

#### Summary and conclusions on the minimum effective dose

In connection with registration under Article 34 of the Regulation (EC) No 1107/2009 of the European Parliament and of the Council, no minimum effective dose tests were carried out.

According to the presented efficacy results, the dose of 1.0 L/ha of MEZI 100 SC provided the optimum overall control and should be considered as effective against these number major weeds, for which activity of product is claimed.

### **3.2.3 Efficacy tests (KCP 6.2)**

#### Materials and methods

The applicant submitted 3 reports (in total) showing the results in research into product efficacy carried out in 2023 in Poland in maize. List of these reports is contained in Appendix 1. Trials were carried out in one season because this herbicide contains mesotrione which is a well-known active substance that has been used for many years in agricultural practice.

#### Site

Trials were conducted in different regions of Poland where maize is grown commercially. The experiment was established on a set of complete randomized blocks in 7 replications.

#### Testing unit

Efficacy studies on herbicide MEZI 100 SC were performed in 2023 by:  
SynTech Research Poland Sp. z o.o., ul. Jagiellońska 69/1, 85-027 Bydgoszcz, Poland

#### 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 1/50(4) Weeds in maize

They were carried out on the field in the conditions of natural weeds infestation.

#### Assessment methods

##### Statistical Analysis

All assessment data were analysed by ANOVA (Two-way Analysis of Variance) and Student-Newman-Keuls mean comparison test using 'ARM 21' (Version 2021.7) ( $p=0.05$ ). All data were first tested for homogeneity using Bartlett's test for homogeneity. For any data columns that failed this test, automatic data transformations were conducted in ARM or problematic replicates/treatments were excluded from the analysis (see ARM action codes below each result table). Care should be taken when interpreting these data columns. Efficacy were analysed using Abbott test (% of untreated).

The treatment means of the assessment dates were calculated and compared using Student-Newman-Keuls test ( $P=0.05$ ). The statistical procedures were applied using ARM 2021.2 software.

##### Assessment of efficacy

The effectiveness of the control of dicotyledonous weeds was assessed visually by comparing the condition of individual weeds on the herbicide-treated plots and on the untreated objects. Results were presented as percent damage using a 0-100 scale, where 0 - no efficacy, 100 - total weed control. Both before the application of the preparation and on each evaluation day, the number of individual weeds was determined on the control plots on the area of 1 m<sup>2</sup>.

##### Assessment of phytotoxicity

Phytotoxicity assessments of tested preparations were done by a visual estimation of an intensity of chlorosis, necrosis, leave curling, reduction in turgor of plants etc. found on overall areas of treated plots and by comparison of each treated plot with untreated plot. Assessments were done directly on plantation. Results were shown using 0-100 scale, where: 0 – no phytotoxicity, 100 – total plant destruction.

### Applications methods and rates

The applications were carried out by a BACCAI and SPRBIC.

The product MEZI 100 SC has been used in maize at the following rates of:

1.0 L/ha – postemergence BBCH 14-15.

Callisto 100 SC was used as a reference product in maize.

The experiment was established on a set of complete randomized blocks in 7 replications.

### **Experiment pattern:**

No.	Name	Rate (L/ha)	other rate (g a.s./ha)	Appl code	Growth Stage BBCH
1	Untreated Check				
2	MEZI 100 SC	1.0 L/ha	100 g a.s./ha	A	BBCH 14-15
3	Callisto 100 SC	1.0 L/ha	100 g a.s./ha	A	BBCH 14-15

### Details of experiments

Report code	EU-23-1560-PL01	EU-23-1560-PL02	EU-23-1560-PL03
Location	Naglady/ Poland	Jablowo Paluckie/ Poland	Gaj Mały/ Poland
Plant /cultivar	maize/ SM Perseus	maize/ SY Calo	maize/ Opoka
Seeding date	25.05.2023	10.05.2023	28.04.2023
Seeding rate	90 000 S/ha	82 000 S/ha	83 000 S/ha
Forecrop	potato	maize	maize
Type of sprayer	SPRBIC	BACCAI	BACCAI
Date of treatment	22.06.2023	20.06.2023	09.06.2023
Plant development phase	BBCH 14-16	BBCH 14-15	BBCH 14-15
Soil type	loamy sand	sandy clay loam	sandy loam
pH	5.3	6.5	5.8
Water (L/ha)	200 L/ha	300 L/ha	200 L/ha

Details of agricultural measures, fertilization, and other plant protection products applied during the experiments are included in detailed field study reports listed above.

Summary of the data from effectiveness trials can be found at Appendix 5.

### **Efficacy tests**

The 3 trials have been carried out in maize in 2023 in Poland.

The product MEZI 100 SC has been used in maize in spring at the following rates of:

1.0 L/ha – postemergence BBCH 14-15.

**Table 3.2-10: Details on trial methodology ~~The Mediterranean Zone~~**

<b>Guidelines</b>	General guidelines	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 1/135 (4) Phytotoxicity assessment
	Specific guidelines	PP 1/50(4) Weeds in maize
<b>Experimental design</b>	Plot design	Randomized Complete Block (RCB) – (3)
	Plot size	12.0-15.0 m <sup>2</sup>

	Number of replications	7 (3)
<b>Crop</b>	Trials per crop	Maize (3)
	Varieties per crop	Maize: SM Perseus, SY Calo, Opoka
	Sowing period	28.04.2023-25.05.2023
<b>Application</b>	Crop stage (BBCH)* at application	postemergence: BBCH 14-15
	Timing Pest stage at application (1)	CHEAL BBCH 12-35 ECHCG BBCH 12-23 POLCO BBCH 12-21 POLPE BBCH 12-18 GAETE BBCH 12-21 GASPA BBCH 13-14 CAPBP BBCH 13-22 SETPU BBCH 13-21
	Number of applications Intervals between applications	1 (3 trials), interval – n/a
	Spray volumes	200-300 L/ha
<b>Assessment</b>	Assessment types	Assessment of efficacy Assessment of phytotoxicity
	Assessment dates	2 and 3-4 weeks after application
<b>Other relevant information</b>	e.g. Soil type, pH (in case of soil active substance ...)	Soil type: loamy sand, sandy clay loam, sandy loam pH: 5.3-6.5
	e.g. Natural / artificial inoculation...	n/a
	e.g. Field / Greenhouse...	n/a
	...	n/a

## Maize

A total of 3 trials in Poland were carried out to evaluate the efficacy of product MEZI 100 SC for the control of weeds in maize.

### 3.2.3-1 Efficacy tests of MEZI 100 SC

#### 3.2.3-1.1 The efficacy of MEZI 100 SC in control of CHEAL

##### 14 DA-A

The efficiency of MEZI 100 SC in control of CHEAL were investigated in 3 trials. The tested product at rate: 1.0 L/ha controlled this species of weed at the high level of efficacy 14 DA-A. The effectiveness amounted 87.67%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 90.40% for Callisto 100 SC during the assessment (Appendix 5 tab. 1).

##### 28 DA-A

The efficiency of MEZI 100 SC in control of CHEAL were investigated in 3 trials. The tested product at rate: 1.0 L/ha controlled this species of weed at the high level of efficacy 28 DA-A. The effectiveness amounted 97.97%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 98.47% for Callisto 100 SC during the assessment (Appendix 5 tab. 2).

#### 3.2.3-1.2 The efficacy of MEZI 100 SC in control of ECHCG

##### 14 DA-A

The efficiency of MEZI 100 SC in control of ECHCG were investigated in 3 trials. The tested product at rate: 1.0 L/ha controlled this species of weed at the medium level of efficacy 14 DA-A. The effectiveness amounted 71.20%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 74.07% for Callisto 100 SC during the assessment (Appendix 5 tab. 3).

#### **28 DA-A**

The efficiency of MEZI 100 SC in control of ECHCG were investigated in 3 trials. The tested product at rate: 1.0 L/ha controlled this species of weed at the medium level of efficacy 28 DA-A. The effectiveness amounted 79.53%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 80.70% for Callisto 100 SC during the assessment (Appendix 5 tab. 4).

### **3.2.3-1.3 The efficacy of MEZI 100 SC in control of POLCO**

#### **14 DA-A**

The efficiency of MEZI 100 SC in control of POLCO were investigated in 3 trials. The tested product at rate: 1.0 L/ha controlled this species of weed at the medium level of efficacy 14 DA-A. The effectiveness amounted 75.47%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 79.30% for Callisto 100 SC during the assessment (Appendix 5 tab. 5).

#### **28 DA-A**

The efficiency of MEZI 100 SC in control of POLCO were investigated in 3 trials. The tested product at rate: 1.0 L/ha controlled this species of weed at the high level of efficacy 28 DA-A. The effectiveness amounted 85.60%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 87.70% for Callisto 100 SC during the assessment (Appendix 5 tab. 6).

### **3.2.3-1.4 The efficacy MEZI 100 SC in control of POLPE**

#### **14 DA-A**

The efficiency of MEZI 100 SC in control of POLPE were investigated in 2 trials. The tested product at rate: 1.0 L/ha controlled this species of weed at the medium level of efficacy 14 DA-A. The effectiveness amounted 76.45%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 79.65% for Callisto 100 SC during the assessment (Appendix 5 tab. 7).

#### **28 DA-A**

The efficiency of MEZI 100 SC in control of POLPE were investigated in 2 trials. The tested product at rate: 1.0 L/ha controlled this species of weed at the high level of efficacy 28 DA-A. The effectiveness amounted 89.20%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 89.50% for Callisto 100 SC during the assessment (Appendix 5 tab. 8).

### **3.2.3-1.5 The efficacy of MEZI 100 SC in control of GAETE**

#### **14 DA-A**

The efficiency of MEZI 100 SC in control of GAETE were investigated in 1 trial. The tested product at rate: 1.0 L/ha controlled this species of weed at the medium level of efficacy 14 DA-A. The effectiveness amounted 84.30%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 84.30% for Callisto 100 SC during the assessment (Appendix 5 tab. 9).

#### **28 DA-A**

The efficiency of MEZI 100 SC in control of GAETE were investigated in 1 trial. The tested product at rate: 1.0 L/ha controlled this species of weed at the high level of efficacy 28 DA-A. The effectiveness amounted 100%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 100% for Callisto 100 SC during the assessment (Appendix 5 tab. 10).

#### **3.2.3-1.6 The efficacy of MEZI 100 SC in control of GASPA**

##### **14 DA-A**

The efficiency of MEZI 100 SC in control of GASPA were investigated in 1 trial. The tested product at rate: 1.0 L/ha controlled this species of weed at the high level of efficacy 14 DA-A. The effectiveness amounted 85.00%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 88.60% for Callisto 100 SC during the assessment (Appendix 5 tab. 11).

##### **28 DA-A**

The efficiency of MEZI 100 SC in control of GASPA were investigated in 1 trial. The tested product at rate: 1.0 L/ha controlled this species of weed at the high level of efficacy 28 DA-A. The effectiveness amounted 99.00%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 99.00% for Callisto 100 SC during the assessment (Appendix 5 tab. 12).

#### **3.2.3-1.7 The efficacy of MEZI 100 SC in control of CAPBP**

##### **14 DA-A**

The efficiency of MEZI 100 SC in control of CAPBP were investigated in 2 trials. The tested product at rate: 1.0 L/ha controlled this species of weed at the medium level of efficacy 14 DA-A. The effectiveness amounted 83.95%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 83.60% for Callisto 100 SC during the assessment (Appendix 5 tab. 13).

##### **28 DA-A**

The efficiency of MEZI 100 SC in control of CAPBP were investigated in 2 trials. The tested product at rate: 1.0 L/ha controlled this species of weed at the high level of efficacy 28 DA-A. The effectiveness amounted 96.65%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 95.95% for Callisto 100 SC during the assessment (Appendix 5 tab. 14).

#### **3.2.3-1.8 The efficacy of MEZI 100 SC in control of SETPU**

##### **14 DA-A**

The efficiency of MEZI 100 SC in control of SETPU were investigated in 1 trial. The tested product at rate: 1.0 L/ha controlled this species of weed at the low level of efficacy 14 DA-A. The effectiveness amounted 0.00%.

The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 0.00% for Callisto 100 SC during the assessment (Appendix 5 tab. 15).

##### **28 DA-A**

The efficiency of MEZI 100 SC in control of SETPU were investigated in 1 trial. The tested product at rate: 1.0 L/ha controlled this species of weed at the low level of efficacy 28 DA-A. The effectiveness amounted 0.00%.



The efficacy of the tested herbicide was comparable to the standard product. In the trials efficacy amounted above 0.00% for Callisto 100 SC during the assessment (Appendix 5 tab. 16).

**Table 3.2-11a: Efficacy of product MEZI 100 SC at the 14 DA-A.**

Target	Grouping*	Number of trials	Infestation of the un-treated control (pcs./m <sup>2</sup> )			% control with MEZI 100 SC			% control with Callisto 100 SC			No of trials where product is >, <, = compared to stand-ard(s)**
						1.0 L/ha			1.0 L/ha			
			Mean	Min & Max		Mean	Min & Max		Mean	Min & Max		
weeds	CHEAL	3	17.0	11.9	27.0	87.67	81.40	98.70	90.40	84.40	98.90	-
	ECHCG	3	29.5	8.0	69.3	71.20	60.00	83.60	74.07	66.40	82.90	-
	POLCO	3	7.2	5.6	9.1	75.47	72.10	80.00	79.30	75.00	83.60	-
	POLPE	2	6.5	6.0	7.0	76.45	75.00	77.90	79.65	76.40	82.90	-
	GAETE	1	5.4	5.4	5.4	84.30	84.30	84.30	84.30	84.30	84.30	-
	GASPA	1	10.0	10.0	10.0	85.00	85.00	85.00	88.60	88.60	88.60	-
	CAPBP	2	6.7	5.3	8.0	83.95	80.00	87.90	83.60	77.90	89.30	-
	SETPU	1	20.9	20.9	20.9	0.00	0.00	0.00	0.00	0.00	0.00	-

\* A, B, C can be a “trial group” (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:

- to add lines or columns,

- to duplicate the table (e.g. one table for “trial group 1”, one table for “trial group 2”, one table for “all”).

\*\* Optional

**Table 3.2-11b: Efficacy of product MEZI 100 SC at the 28 DA-A.**

Target	Grouping*	Number of trials	Infestation of the untreated control (unit)			% control with MEZI 100 SC			% control with Callisto 100 SC			No of trials where product is >, <, = compared to standard(s)**
						1.0 L/ha			1.0 L/ha			
			Mean	Min & Max		Mean	Min & Max		Mean	Min & Max		
weeds	CHEAL	3	36.1	12.1	69.3	97.97	96.60	100.00	98.47	96.40	100.00	-
	ECHCG	3	29.5	8.0	69.2	79.53	77.90	80.70	80.70	75.70	87.10	-
	POLCO	3	7.2	5.6	9.1	85.60	77.10	98.30	87.70	77.10	98.10	-
	POLPE	2	6.5	6.0	7.0	89.20	80.00	98.40	89.50	80.00	99.00	-
	GAETE	1	5.4	5.4	5.4	100.00	100.00	100.00	100.00	100.00	100.00	-
	GASPA	1	10.0	10.0	10.0	99.00	99.00	99.00	99.00	99.00	99.00	-
	CAPBP	2	6.7	5.3	8.0	96.65	94.30	99.00	95.95	92.90	99.00	-
	SETPU	1	20.9	20.9	20.9	0.00	0.00	0.00	0.00	0.00	0.00	-

\* A, B, C can be a “trial group” (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:

- to add lines or columns,

- to duplicate the table (e.g. one table for “trial group 1”, one table for “trial group 2”, one table for “all”).

\*\* Optional

## Minor use

Not applicable

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

Not applicable

## Summary and conclusion

The submitted efficacy data (reports from 3 field trials) and additional information fulfil requirements and conditions determined in the following EPPO guidelines:

- PP 1/135 (3) Phytotoxicity assessment

- PP 1/152 (3) Design and analysis of efficacy evaluation trials

- PP 1/181 (3) Conduct and reporting of efficacy evaluation trials including good experimental practice

They were carried out on the field in the conditions of natural agrofag infestation. The efficacy trials were concluded according to the EPPO standards:

- PP 1/50(4) Weeds in maize

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 formulation of MEZI 100 SC is Suspension concentrate (SC) and it comprises active substance 100 g/L mesotrione. The applicant submitted 3 reports in total showing the results in research into product efficacy carried out in 2023 in maize.

The obtained data in performed trials show that MEZI 100 SC provides benefits against the most important weeds in maize, as shown in the table below.

The table shows the effectiveness of the herbicide MEZI 100 SC for the experiments from Poland.

The following table describes the effectiveness of weeds

Efficacy
Susceptible (S) 85-100%
Moderately Susceptible (MS) 70-84.9%
Moderately Tolerant (MT) 50-69.9%
Tolerant (T) 0-49.9 %

The table shows the effectiveness of the herbicide MEZI 100 SC 14 DA-A for the experiments from Poland.

Product code (L, kg/ha)	EPPO code	Scientific name	DA-A	Pest stage	Average	Efficacy
MEZI 100 SC	CHEAL	<i>Chenopodium album</i>	14 DA-A	BBCH 12-35	87.67	S
	ECHCG	<i>Echinochola crus-galli</i>	14 DA-A	BBCH 12-23	71.20	MS
	POLCO	<i>Polygonum convovulus</i>	14 DA-A	BBCH 12-21	75.47	MS
	POLPE	<i>Polygonum persicaria</i>	14 DA-A	BBCH 12-18	76.45	MS
	GAETE	<i>Galeopsis tetrahit</i>	14 DA-A	BBCH 12-21	84.30	MS
	GASPA	<i>Galinsoga parviflora</i>	14 DA-A	BBCH 13-14	85.00	S
	CAPBP	<i>Capsella bursa-pastoris</i>	14 DA-A	BBCH 13-22	83.95	MS
	SETPU	<i>Setaria pumila</i>	14 DA-A	BBCH 13-21	0.00	T
Callisto 100 SC	CHEAL	<i>Chenopodium album</i>	14 DA-A	BBCH 12-35	90.40	S
	ECHCG	<i>Echinochola crus-galli</i>	14 DA-A	BBCH 12-23	74.07	MS
	POLCO	<i>Polygonum convovulus</i>	14 DA-A	BBCH 12-21	79.30	MS

	POLPE	<i>Polygonum persicaria</i>	14 DA-A	BBCH 12-18	79.65	MS
	GAETE	<i>Galeopsis tetrahit</i>	14 DA-A	BBCH 12-21	84.30	MS
	GASPA	<i>Galisnoga parviflora</i>	14 DA-A	BBCH 13-14	88.60	S
	CAPBP	<i>Capsella bursa-pastoris</i>	14 DA-A	BBCH 13-22	83.60	MS
	SETPU	<i>Setaria pumila</i>	14 DA-A	BBCH 13-21	0.00	T

On the basis of submitted research, it is possible to state that the MEZI 100 SC controlled maize at level:

**MEZI 100 SC 1.0 L/ha**

Susceptible: *Chenopodium album*, *Galisnoga parviflora*

Moderately Susceptible: *Echinochola crus-galli*, *Polygonum convovulus*, *Polygonum persicaria*, *Galeopsis tetrahit*, *Capsella bursa-pastoris*

Tolerant: *Setaria pumila*

The table shows the effectiveness of the herbicide MEZI 100 SC 28 DA-A for the experiments from Poland.

Product code (L, kg/ha)	EPPO code	Scientific name	DA-A	Pest stage	Average	Efficacy
MEZI 100 SC	CHEAL	<i>Chenopodium album</i>	28- DA-A	BBCH 12-35	97.97	S
	ECHCG	<i>Echinochola crus-galli</i>	28- DA-A	BBCH 12-23	79.53	MS
	POLCO	<i>Polygonum convovulus</i>	28- DA-A	BBCH 12-21	85.60	S
	POLPE	<i>Polygonum persicaria</i>	28- DA-A	BBCH 12-18	89.20	S
	GAETE	<i>Galeopsis tetrahit</i>	28- DA-A	BBCH 12-21	100.00	S
	GASPA	<i>Galisnoga parviflora</i>	28- DA-A	BBCH 13-14	99.00	S
	CAPBP	<i>Capsella bursa-pastoris</i>	28- DA-A	BBCH 13-22	96.65	S
	SETPU	<i>Setaria pumila</i>	28- DA-A	BBCH 13-21	0.00	T
Callisto 100 SC	CHEAL	<i>Chenopodium album</i>	28- DA-A	BBCH 12-35	98.47	S
	ECHCG	<i>Echinochola crus-galli</i>	28- DA-A	BBCH 12-23	80.70	MS
	POLCO	<i>Polygonum convovulus</i>	28- DA-A	BBCH 12-21	87.70	S
	POLPE	<i>Polygonum persicaria</i>	28- DA-A	BBCH 12-18	89.50	S
	GAETE	<i>Galeopsis tetrahit</i>	28- DA-A	BBCH 12-21	100.00	S
	GASPA	<i>Galisnoga parviflora</i>	28- DA-A	BBCH 13-14	99.00	S
	CAPBP	<i>Capsella bursa-pastoris</i>	28- DA-A	BBCH 13-22	95.95	S
	SETPU	<i>Setaria pumila</i>	28- DA-A	BBCH 13-21	0.00	T

On the basis of submitted research, it is possible to state that the MEZI 100 SC controlled maize at level:

**MEZI 100 SC 1.0 L/ha**

Susceptible: *Chenopodium album*, *Galisnoga parviflora*, *Polygonum convovulus*, *Polygonum persicaria*, *Galeopsis tetrahit*, *Capsella bursa-pastoris*

Moderately Susceptible: *Echinochola crus-galli*,

Tolerant: *Setaria pumila*

The carried out trials confirm that MEZI 100 SC has the same high efficacy as Callisto 100 SC against the same weed spectrum.

dRR point 3.2.3	ZRMS conclusion								
<p style="text-align: center;"><b>Control of weeds in PL</b></p> <p>To support authorization of the product MEZI 100 SC considering Art. 34 of the Regulation 1107/2009, the applicant submitted 3 bridging trials carried out in maize in 2023, in three regions of Poland. Efficacy of the product against 8 species of weeds were tested in the submitted trials . Crop stage at application was BBCH 14-15. In trials used 200-300 l spray volume per ha.</p> <p>The reference product to whose unprotected data the applicant refers is Callisto 100 SC.</p> <p>Efficacy trials were carried out by organizations that are officially recognized as competent to carry out efficacy testing in accordance with Regulation (EC) 284/2013. All trials have been conducted according to GEP.</p> <p>The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:</p> <ol style="list-style-type: none"> <li>1. PP 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice.</li> <li>2. PP 1/135 (4) Phytotoxicity assessment</li> <li>3. PP 1/152 (4) Design and analysis of efficacy evaluation trials</li> <li>4. PP 1/50 (4) Weeds in maize</li> </ol> <p>Trials were of randomized block design with a minimum of seven replicates.</p> <p><u>Weed species are classified as:</u></p> <table> <tr> <td>susceptible (S) –</td><td>85%</td></tr> <tr> <td>moderately susceptible (MS) -</td><td>70-85%</td></tr> <tr> <td>moderately tolerant (MT)</td><td>60 -70%</td></tr> <tr> <td>tolerant (T)</td><td>&lt; 60%</td></tr> </table> <p>The tested product and the reference product were applied at the rate 1,0 l/ha.</p> <p>In all bridging trials, the efficacy of the product tested was comparable to the reference product Callisto 100 SC. The both products in the bridging trials showed comparable efficacy against dicots in comparison to the efficacy of dicots weeds presented on the reference product label (Callisto 100 SC). What is more, both products showed lower efficacy against ECHCG (28 DAA, 3 trials), compared to ECHCG susceptibility classification presented on the label currently authorised reference product Callisto 100 SC (the only monocotyledonous weed species included on the reference product label).</p> <p>It is proposed to include the ECHCG classification on the MEZI 100 SC label according to the results of the bridging trials presented (MS) and placed classification of the dicots weeds as it is presented on the reference product label.</p> <p>Taking into account above, unprotected data of Callisto 100 SC can be used to support the authorisation of MEZI 100 SC.</p>		susceptible (S) –	85%	moderately susceptible (MS) -	70-85%	moderately tolerant (MT)	60 -70%	tolerant (T)	< 60%
susceptible (S) –	85%								
moderately susceptible (MS) -	70-85%								
moderately tolerant (MT)	60 -70%								
tolerant (T)	< 60%								

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

**Resistance Risk Assessment** (*according to EPPO PP 1/213 (4) Resistance risk analysis*)

#### **3.3.1 Mode of action**

MEZI 100 SC is a herbicide containing active substance mesotrione 100 g/L. Mesotrione belongs to the chemical group of the triketones (2-benzylcyclohexane-1,3-diones), which acts by blocking the function of the essential plant enzyme 4-hydroxy-phenyl-pyruvate dioxygenase (4-HPPD) in the cytosol of sensitive plants. Mesotrione is a systemic herbicide and controls most annual broadleaf and annual grass weed species in maize. It is taken up via roots and shoots and translocated rapidly in both the xylem and phloem into all plant parts. In sensitive plants symptoms of white chlorosis become visible within a few days after application in actively growing tissues being in the cell elongation phase. Complete death of sensitive plants may occur up to 2 weeks after application.

#### **3.3.2 Mechanism of resistance**

MEZI 100 SC is a herbicide containing active substance mesotrione 100 g/L, which belong to HRAC group 27 – 4-HPPD inhibitors. According HRAC Resistance of weed biotypes to herbicides is a consequence of naturally occurring mutations and evolutionary processes. Individuals within a species that are best adapted and not susceptible to a particular practice, such as application of a specific herbicide, are selected for and will increase in the population. Mitigating or slowing the evolution of herbicide resistance relies on reducing selection pressure for resistance through application of a diversity of weed management practices. There are two general categories of resistance mechanisms, target-site resistance and non-target-site resistance. Target-site resistance inhibits herbicide action by: a change in structure of the target protein that decreases herbicide binding to its usual site of action; an increase in target protein expression; or an increase in copies of the gene containing the target site. Non-target-site resistance includes decreased translocation of an herbicide to its site of action, increased metabolic detoxification of an herbicide, and sequestration or immobilization of an herbicide in a part of the plant so it cannot reach its site of action. Resistance to HPPD herbicides is determined by a non-target site mechanism.

According to EPPO PP 1/213 (4) Resistance risk analysis weeds usually only produce one generation per year and development of resistance is usually a relatively slow process. It is difficult to class any weed species as inherently more or less likely to develop resistance to a particular herbicide.

#### **3.3.3 Evidence of resistance**

Mesotrione belongs to HRAC group 27 (Legacy F2). According to Ian Heap's website (<http://www.weedscience.org>) there are only three species which have been reported as resistant to HRAC group 27 (Legacy F2). These are *Amaranthus palmeri*, *Amaranthus tuberculatus* (= *A. rudis*) and *Raphanus raphanistrum*. All cases reported have been in the United States and Australia with no evidence of resistance in Europe. Overall the risk of resistance development to HRAC group 27 (Legacy F2) is low.

According to <https://weedsience.org/>:

Table 1. Herbicide resistance cases to 4-HPPD inhibitors

Year	Species	Country	Actives	Crops
2009	<i>Amaranthus tuberculatus</i> (=A. rudis)	United States	imazethapyr, chlorimuron-ethyl, atrazine, mesotrione, tembotrione, topramezone	Seed corn
2009	<i>Amaranthus tuberculatus</i> (=A. rudis)	United States	thifensulfuron-methyl, rimsulfuron, atrazine, mesotrione, tembotrione, topramezone	Seed corn
2009	<i>Amaranthus palmeri</i>	United States	thifensulfuron-methyl, atrazine, mesotrione, pyrasulfotole, tembotrione, topramezone	Corn (maize), Sorghum
2011	<i>Amaranthus tuberculatus</i> (=A. rudis)	United States	imazamethabenz-methyl, thifensulfuron-methyl, chlorimuron-ethyl, atrazine, isoxaflutole, glyphosate, mesotrione	Corn (maize), Soybean
2011	<i>Amaranthus tuberculatus</i> (=A. rudis)	United States	mesotrione, tembotrione, topramezone	Corn (maize)
2011	<i>Amaranthus palmeri</i>	United States	mesotrione, tembotrione, topramezone	Corn (maize)
2014	<i>Amaranthus palmeri</i>	United States	atrazine, mesotrione, tembotrione, topramezone	Corn (maize)
2014	<i>Amaranthus palmeri</i>	United States	imazethapyr, thifensulfuron-methyl, tembotrione	Corn (maize)
2015	<i>Raphanus raphanistrum</i>	Australia	chlorsulfuron, atrazine, diflufenican, fluridone, isoxaflutole, 2,4-D, mesotrione, tembotrione	Wheat
2015	<i>Amaranthus palmeri</i>	United States	chlorsulfuron, atrazine, glyphosate, 2,4-D, mesotrione	Sorghum
2016	<i>Amaranthus tuberculatus</i> (=A. rudis)	United States	imazethapyr, chlorimuron-ethyl, atrazine, fomesafen, lactofen, acifluorfen, 2,4-D, mesotrione, tembotrione, topramezone	Corn (maize), Soybean
2016	<i>Amaranthus palmeri</i>	United States	mesotrione	Corn (maize)
2020	<i>Raphanus raphanistrum</i>	Australia	metsulfuron-methyl, dicamba, 2,4-D, mesotrione, topramezone, pyroxasulfone	Wheat
2020	<i>Amaranthus tuberculatus</i> (=A. rudis)	United States	imazethapyr, atrazine, fomesafen, glyphosate, mesotrione	Soybean

### 3.3.4 Cross-resistance

According to <https://hracglobal.com/files/Herbicide-Cross-Resistance-and-Multiple-Resistance-in-Plants.pdf>

Cross resistance is defined as the expression of a genetically-endowed mechanism conferring the ability to withstand herbicides from different chemical classes. There are two broad cross resistance categories; target site cross resistance and non-target site cross resistance.

Target site cross resistance occurs when a change at the biochemical site of action of one herbicide also confers resistance to herbicides from a different chemical class that inhibit the same site of action in the plant. Target site cross resistance does not necessarily result in resistance to all herbicide classes with a similar mode of action or indeed all herbicides within a given herbicide class.

Non target site cross resistance is defined as cross resistance to dissimilar herbicide classes conferred by a mechanism(s) other than resistant enzyme target sites. Until recently documented for *L. rigidum* and *A. myosuroides*, non-target site cross resistance was largely unknown in herbicide-resistant weeds but is well known in the insecticide resistance literature (Brattsten et al., 1986; Georgiou, 1986).

Cross resistance occurs mainly in the group of ALS inhibitors, acetyl-CoA carboxylase (ACCase)-inhibitors and photosystem two (PS2)-inhibitors. There is no evidence to cross resistance to 4-HPPD inhibitors, including mesotrione.

### **3.3.5 Sensitivity data**

Applicant didn't conduct separately trials for sensitivity data, this data was evaluated in efficacy trials. The 3 field trials use were established in order to determine the sensitivity of weeds in maize. The MEZI 100 SC was tested at doses: 1.0 L/ha in maize for the control of mono and dicot weeds. None of the tested weeds showed high tolerance to the product MEZI 100 SC. Detailed studies on the weeds sensitivity are submitted and summarised in 3.2 Efficacy data (KCP 6).

### **3.3.6 Use pattern**

Herbicide MEZI 100 SC has demonstrated good crop tolerance to maize. Therefore concluded that MEZI 100 SC is safe usage at proposed rate and this support the label claim for the use in maize.

According to the above, the plant protection product MEZI 100 SC can be approved to the market and use in Poland according to proposed range of use – GAP

Based on submitted data the following regulation on the label is proposed:

MEZI 100 SC is to be applied in spring in maize:

postemergence: BBCH 14-15 in recommended dose at 1.0 L/ha

Recommended volume of water 200-300 L/ha

Recommended medium droplet spraying

To avoid resistance, products contain active substance with the same group shouldn't be used year after year on the same field.

### **3.3.7 Resistance risk assessment of unrestricted use pattern**

Not applicable

### **3.3.8 Test methods**

Not applicable

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

Mesotrione belongs to the chemical group of the triketones (2-benzylcyclohexane-1,3-diones), which acts by blocking the function of the essential plant enzyme 4-hydroxy-phenyl-pyruvate dioxygenase (4-HPPD) in the cytosol of sensitive plants. Mesotrione is a systemic herbicide and controls most annual broadleaf and annual grass weed species in maize. It is taken up via roots and shoots and translocated rapidly in both the xylem and phloem into all plant parts. In sensitive plants symptoms of white chlorosis become visible within a few days after application in actively growing tissues being in the cell elongation phase. Complete death of sensitive plants may occur up to 2 weeks after application. Maize has a natural tolerance against mesotrione as it can detoxify the herbicide into inactive compounds. This detoxification is mediated by cytochrome-P450-oxygenase and is so rapid in maize that mesotrione is not translocated away from the

treated zone to the point of action. Sensitive weed species cannot detoxify mesotrione in this way. Mesotrione belongs to HRAC group 27 (Legacy F2). According to Ian Heap's website (<http://www.weedscience.org>) there are only three species which have been reported as resistant to HRAC group 27 (Legacy F2). These are *Amaranthus palmeri*, *Amaranthus tuberculatus* (=A. *rudis*) and *Raphanus raphanistrum*. All cases reported have been in the United States and Australia with no evidence of resistance in Europe.

According to submitted efficacy data none of the tested weeds showed high tolerance to the product MEZI 100 SC.

According to EPPO PP 1/213 (4) Resistance risk analysis weeds usually only produce one generation per year and development of resistance is usually a relatively slow process.

According to *Raport oceniający dokumentację wniosku rejestracyjnego herbicydu Callisto 100 SC w zakresie skuteczności i fitotoksyczności* the risk of weed resistance occurring is low.

In conclusion, in the applicant's opinion, this level of weeds resistance risk should be considered to be acceptable.

### 3.3.10 Management strategy

According to *Herbicide Resistance Action Committee (HRAC)* (<https://hracglobal.com/prevention-management/best-management-practices>)

Integrated Weed Management (IWM) refers to using chemical, cultural, mechanical and biological methods, in an integrated fashion, to control weeds. It does not rely excessively on any one method. When used in a integrated approach, the following tools help reduce selection pressure and survival of resistant weeds.

- Chemical - Applying herbicides to a crop.
- Mechanical - Includes measures such as hand-weeding using cultivation or ploughing to control emerged plants and bury non-germinated seed. It also includes harvest weed seed destruction such as stubble burning and cutting for hay or silage to prevent the weeds from setting seed.
- Cultural - Includes altering the crop planting date, row spacing and harvest timing to disrupt the weed cycle. It also includes planting crops that can out-compete weeds, buying certified seed that's free of weeds and using a diverse crop rotation. Growers should also sanitize farm equipment when moving between fields.
- Biological - Includes introducing insects and pathogens that control target weed species and introducing post-harvest grazing of growing weeds.

Using a diversified crop rotation allows farmers to use these different weed techniques. Avoid successive crops that use herbicides with the same mechanism of action to control the same weed species in the same field.

Guidelines for the sustainable use of herbicide site of action groups:

- Use mixtures or sequential treatments of herbicides having different sites of action. Each herbicide in the mixture should target the same weed species.
- Consider all chemical control options before planting, in-crop and after harvest.
- Avoid continued use of the same herbicides, or herbicides with the same site of action in the same field, unless integrated with other weed control practices.
- Limit the number of applications of a single herbicide or herbicides with the same site of action in a single growing season.
- Herbicide mixtures and herbicide rotations alone are not enough to prevent resistance. They must be used in a diversified plan than also incorporates mechanical, cultural and biological practices.

Growers should also do the following:

- Follow label use instructions, such as application rates, timing and equipment recommendations.



- Know the weeds in their fields and nearby non-crop areas and tailor their weed control program to weed densities and economic thresholds.
- Monitor herbicide results and be aware of any trends or changes in weed populations.
- Maintain detailed field records to confirm cropping and herbicide history.

### **3.3.11 Implementation of the management strategy**

The herbicide label provides all the necessary information for preventing weed resistance to herbicides.

### **3.3.12 Monitoring, reporting and reaction to changes in performance**

*According to <https://hracglobal.com/files/Monitoring-and-Mitigation-of-Herbicide-Resistance.pdf>*

Managing the risk of herbicide resistance (HR) is an area of strategic importance for leading herbicide technology providers and is the focus of the Global Herbicide Resistance Action Committee (HRAC), an organization comprised of 8 major companies working as a part of Crop Life International. Early detection of HR, understanding the scope of HR in a defined area, and potential mitigation of resistance through efforts to limit its spread are important aspects of managing the risk of HR. Monitoring for HR populations has been employed by public and private weed scientists for both early detection and defining the scope of resistance. The primary methods used to monitor for resistance include:

- 1) field surveys where seed from putative resistant plants are collected and tested in a controlled environment using bioassay procedures,
- 2) market research surveys of farmers and weed management experts, and
- 3) tracking farmer performance inquiries with appropriate follow up field evaluation and testing.

The most common monitoring method is the use of field surveys designed to either qualitatively (i.e., determine whether the level of resistance is high, medium, or low) or quantitatively (i.e., determine the area infested with HR populations) define existing HR. The primary method to detect resistance in new species and in new geographies is to track farmer performance inquiries. Once resistance is detected, steps may be taken to mitigate its impact. A critical aspect to mitigation is the implementation of best management practices (BMPs) which is facilitated by effective education and training programs. Education efforts can be enhanced with information obtained from monitoring studies and early detection of resistant populations using appropriate monitoring methods can improve the outcome of mitigation efforts.

dRR point 3.3	ZRMS conclusion
According to <a href="https://www.weedscience.com/Home.aspx">https://www.weedscience.com/Home.aspx</a> , no resistant strains of weed species have been reported so far in Europe. Nevertheless, to prevent weeds resistance development, the label of the product should contain recommendations of HRAC resistance management.	

### 3.4 Adverse effects on treated crops (KCP 6.4)

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

**Table 3.4-1: Presentation of trials selectivity trials.**

Crop*	Country	Type of trial**	Number of trials	Years	GEP, non-GEP, official***	Comments (any other relevant information)
			North-East Zone			
maize	Poland	S	3	2023	GEP	-
<b>TOTAL</b>	-	-	<b>3</b>	-	-	-

\* 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

\*\*\* Official: carried out by a national official organisation

**Table 3.4-2: Presentation of reference standards used in selectivity trials (selectivity trials, transformation trials...)**

Crop(s)	Reference standard	Country(ies) where the product is registered <sup>(1)</sup>	Authorization number	Active substance(s)	Formulation		Registered application rate <sup>(3)</sup>	Application rate in trials (per treatment)	Remark <sup>(4)</sup>
					Type <sup>(2)</sup>	Concentration of a.s.			
maize	Callisto 100 SC	Poland	R-990/2020d	mesotrione	SC — Suspension concentrate	100 g/L	1.0 L/ha	1.0 L/ha	-

(1) only on use(s) applied for (with the test product)

(2) e.g. WP (wetable 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...)

#### 3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

##### Materials and methods

The applicant submitted 3 reports (in total) showing the results in research into product efficacy carried out in 2023 in Poland in maize. List of these reports is contained in Appendix 1. Trials were carried out in one season because this herbicide contains mesotrione which is a well-known active substance that has been used for many years in agricultural practice.

##### Site

Trials were conducted in different regions of Poland where maize is grown commercially. The experiment was established on a set of complete randomized blocks in 7 replications.

##### Testing unit

Efficacy studies on herbicide MEZI 100 SC were performed in 2023 by:

SynTech Research Poland Sp. z o.o., ul. Jagiellońska 69/1, 85-027 Bydgoszcz, Poland

##### 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 1/50(4) Weeds in maize

#### Assessment methods

##### Statistical Analysis

All assessment data were analysed by ANOVA (Two-way Analysis of Variance) and Student-Newman-Keuls mean comparison test using 'ARM 21' (Version 2021.7) ( $p=0.05$ ). All data were first tested for homogeneity using Bartlett's test for homogeneity. For any data columns that failed this test, automatic data transformations were conducted in ARM or problematic replicates/treatments were excluded from the analysis (see ARM action codes below each result table). Care should be taken when interpreting these data columns. Efficacy were analysed using Abbott test (% of untreated).

The treatment means of the assessment dates were calculated and compared using Student-Newman-Keuls test ( $P=0.05$ ). The statistical procedures were applied using ARM 2021.2 software.

##### Assessment of phytotoxicity

Phytotoxicity assessments of tested preparations were done by a visual estimation of an intensity of chlorosis, necrosis, leave curling, reduction in turgor of plants etc. found on overall areas of treated plots and by comparison of each treated plot with untreated plot. Assessments were done directly on plantation. Results were shown using 0-100 scale, where: 0 – no phytotoxicity, 100 – total plant destruction.

##### Applications methods and rates

The applications were carried out by a BACCAI and SPRBIC.

The product MEZI 100 SC has been used in maize at the following rates of:

1.0 L/ha – postemergence BBCH 14-15.

Callisto 100 SC was used as a reference product in maize.

The experiment was established on a set of complete randomized blocks in 7 replications.

#### **Experiment pattern:**

No.	Name	Rate (L/ha)	other rate (g a.s./ha)	Appl code	Growth Stage BBCH
1	Untreated Check				
2	MEZI 100 SC	1.0 L/ha	100 g a.s./ha	A	BBCH 14-15
3	Callisto 100 SC	1.0 L/ha	100 g a.s./ha	A	BBCH 14-15

#### Details of experiments

Report code	EU-23-1560-PL01	EU-23-1560-PL02	EU-23-1560-PL03
Location	Naglady/ Poland	Jablowo Paluckie/ Poland	Gaj Mały/ Poland
Plant /cultivar	maize/ SM Perseus	maize/ SY Calo	maize/ Opoka
Seeding date	25.05.2023	10.05.2023	28.04.2023
Seeding rate	90 000 S/ha	82 000 S/ha	83 000 S/ha
Forecrop	potato	maize	maize
Type of sprayer	SPRBIC	BACCAI	BACCAI
Date of treatment	22.06.2023	20.06.2023	09.06.2023
Plant development phase	BBCH 14-16	BBCH 14-15	BBCH 14-15
Soil type	loamy sand	sandy clay loam	sandy loam
pH	5.3	6.5	5.8
Water (L/ha)	200 L/ha	300 L/ha	200 L/ha

Details of agricultural measures, fertilization, and other plant protection products applied during the experiments are included in detailed field study reports listed above.

Summary of the data from effectiveness trials can be found at Appendix 6.

**Table 3.4-3: Phytotoxicity of product**

The 3 efficacy trials in maize were carried out in Poland in 2023 on a wide range of commercially grown varieties. There were not observed any phytotoxicity symptoms on tested product and standard in trials.

Number of trials with		Efficacy trials (3)	
		MEZI 100 SC	Callisto 100 SC
		N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	0-3	0-3
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	0	0
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

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

According to *Raport oceniający dokumentację wniosku rejestracyjnego herbicydu Callisto 100 SC w zakresie skuteczności i fitotoksyczności* 4 selectivity trials were conducted on 4 maize varieties Delitop, Lambada, Oldham and Magister. Transient symptoms of phytotoxicity (leaf discolouration, 3-4%) were noted in the trials, but did not affect the maize yield. The reference product Callisto 100 SC is selective and fully safe for maize crops. Compared to untreated objects, the application of Callisto 100 SC resulted in a significant increase in grain yield. Callisto 100 SC herbicide has a positive effect on maize yield.

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

According to *Raport oceniający dokumentację wniosku rejestracyjnego herbicydu Callisto 100 SC w zakresie skuteczności i fitotoksyczności* 4 selectivity trials were conducted on 4 maize varieties Delitop, Lambada, Oldham and Magister. Transient symptoms of phytotoxicity (leaf discolouration, 3-4%) were noted in the trials, but did not affect the quality of the maize yield. Compared to untreated objects, the application of Callisto 100 SC resulted in a significant increase in TGW. Callisto 100 SC herbicide has a positive effect on quality of the maize yield.

dRR point 3.4	ZRMS conclusion
Phytotoxicity of MEZI 100 SC was tested in all 3 efficacy trials. The maximum tested dose rate was 1,0 l/ha. No phytotoxicity symptoms were observed in the efficacy trials. The point (selectivity data, effect on yield and quality of yield) was also completed based on the unprotected data of the reference product Callisto 100 SC. The evaluator has no comments.	

### 3.4.4 Effects on transformation processes (KCP 6.4.4)

Lack of additional tests in this range. Active substance comprising in this product has been applied for many years, not only in Poland but also in the other countries of Europe.

According to *Mesotrione\_RAR\_01\_Volume\_1\_2015-02-23\_san.pdf*

Metabolism studies were conducted with crops representative of two different crop groups (cereal/grass: maize and pulses and oilseeds: peanut and herbicide tolerant (HT) soybean) and based on the commercially recommended use pattern, i.e. pre- or post- and pre- and post-emergence foliar applications. Although the

various metabolites were not unambiguously identified in a number of the new studies the metabolites are sufficiently characterised. The metabolism pathways operating in genetically modified HT soybeans are qualitatively similar to those operating in unmodified crops. The metabolism in maize proceeds via oxidation of mesotrione to 4-hydroxymesotrione and/or MNBA. MNBA is then further metabolised to AMBA and incorporated in to natural products. None of the metabolites are considered significantly more toxic than mesotrione, and absolute levels of all residues in grain were low Therefore the residue definition for monitoring and risk assessment in cereal grains should be set as mesotrione parent only. However, as there are significant residues of AMBA and it's conjugates in forage and fodder, and MNBA is significant in pre-emergence treated forage, for future uses for which these parts of the plant would be fed to animals, for example cereal straw, consideration should be given to including these metabolites in the risk assessment. As the metabolism appears to proceed via a similar pathway in pulses and oilseeds it is appropriate to extend the residue definition for cereals (mesotrione parent only) to pulses and oilseeds for monitoring and risk assessment. Residue levels of MNBA, AMBA and 4/5-hydroxymesotrione may also need to be considered for inclusion in the risk assessment for animal feed commodities. A ruminant, lactating Friesian cow, study using radio-labelled AMBA was assessed for the original approval of mesotrione. As no significant intakes are expected for animals no further data are required.

According to magnitude of residues in plants provided in Section B7 in core dossier no significant residues, i.e. >0.1 mg/kg, were found in maize and therefore processing studies are not required. No further studies have been performed. Therefore, no impact for effects on yeasts or lactic bacteria are predicted.

According *EPPO 1/243 (2) Effects of plant protection products on transformation processes* and Section B7 additional study is not required.

According to *PP1/268(1) 'Study of unintentional effects of plant protection products on fermentation processes and characteristics of wine'* for maize no specific trials are required.

dRR point 3.4.4	ZRMS conclusion
Data no needed when no residues of any of the active ingredients are found at harvest.	

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

There is no information available pointing to presence of any limitations to using of MEZI 100 SC in seed crops of maize.

In accordance with the EPPO standard PP 1/135, data on plant parts for propagation are required if herbicide is applied after BBCH 30 of the crop. MEZI 100 SC is going to be applied at BBCH 14-15 of maize, therefore data is no required.

What is more, the products containing mesotrione have been using for many years and are well proven to have no adverse effects on the viability of progeny seed.

dRR point 3.4.5	ZRMS conclusion
Data are not needed because the product is going to be applied before BBCH 30 of maize.	

## Summary and conclusion

Herbicide MEZI 100 SC has demonstrated good crop tolerance to maize. Therefore concluded that MEZI 100 SC is safe usage at proposed rate and this support the label claim for the use in maize.

Undesirable effects are not expected on part of plants used for propagating purposes and beneficial organisms.

According to the above, the plant protection product MEZI 100 SC can be approved to the market and use in Poland according to proposed range of use – GAP.

Based on submitted data the following regulation on the label is proposed:

Poland

Recommended dose at:

1.0 L/ha of MEZI 100 SC – postemergence application (BBCH 14-15) once a season in maize, which are corresponding to 100 g a.s./ha (mesotrione).

To avoid resistance, products contain active substance with the same group shouldn't be used year after year on the same field.

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

### 3.5.1 Impact on succeeding crops (KCP 6.5.1)

To demonstrate the impact of the MEZI 100 SC on succeeding crops, the applicant shall submit studies in accordance with the EPPO guidance *PP 1/207(2) Effects on succeeding crops* and OECD 208: *Terrestrial plant test: Seedling emergence and growth test*.

Studies in accordance with OECD 208: *Terrestrial plant test: Seedling emergence and growth test* are in progress.

According to *Raport oceniający dokumentację wniosku rejestracyjnego herbicydu Callisto 100 SC w zakresie skuteczności i fitotoksyczności* Callisto 100 SC has been found to biodegrade rapidly and, when used as recommended, completely breaks down in the soil even before maize is harvested and poses no risk to succeeding crops.

After harvesting maize under no-till conditions is recommended for cereals or other grasses. In case of frost or agrophag damage to maize, can be replanted with maize or perennial ryegrass.

dRR point 3.5.1	ZRMS conclusion
In the opinion of ZRMS, additional data are not obligatory in this case. If the applicant wish to present new reports to confirm impact of Mezi 100 SC on succeeding crops it is proposed to submit them postauthorised.	

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

No specific studies were conducted to fill this data point.

According to EPPO 1/256 - Decision-support scheme for the risk assessment for adjacent crops - Toxicity values are compared with predicted environmental concentrations to develop a Toxicity:Exposure-Ratio (TER is calculated as the ED50-value divided by the estimated drift value Appendix 2. Progression to the next tier is warranted if the safety margin is not met, while testing is stopped if the safety margin is met or exceeded.

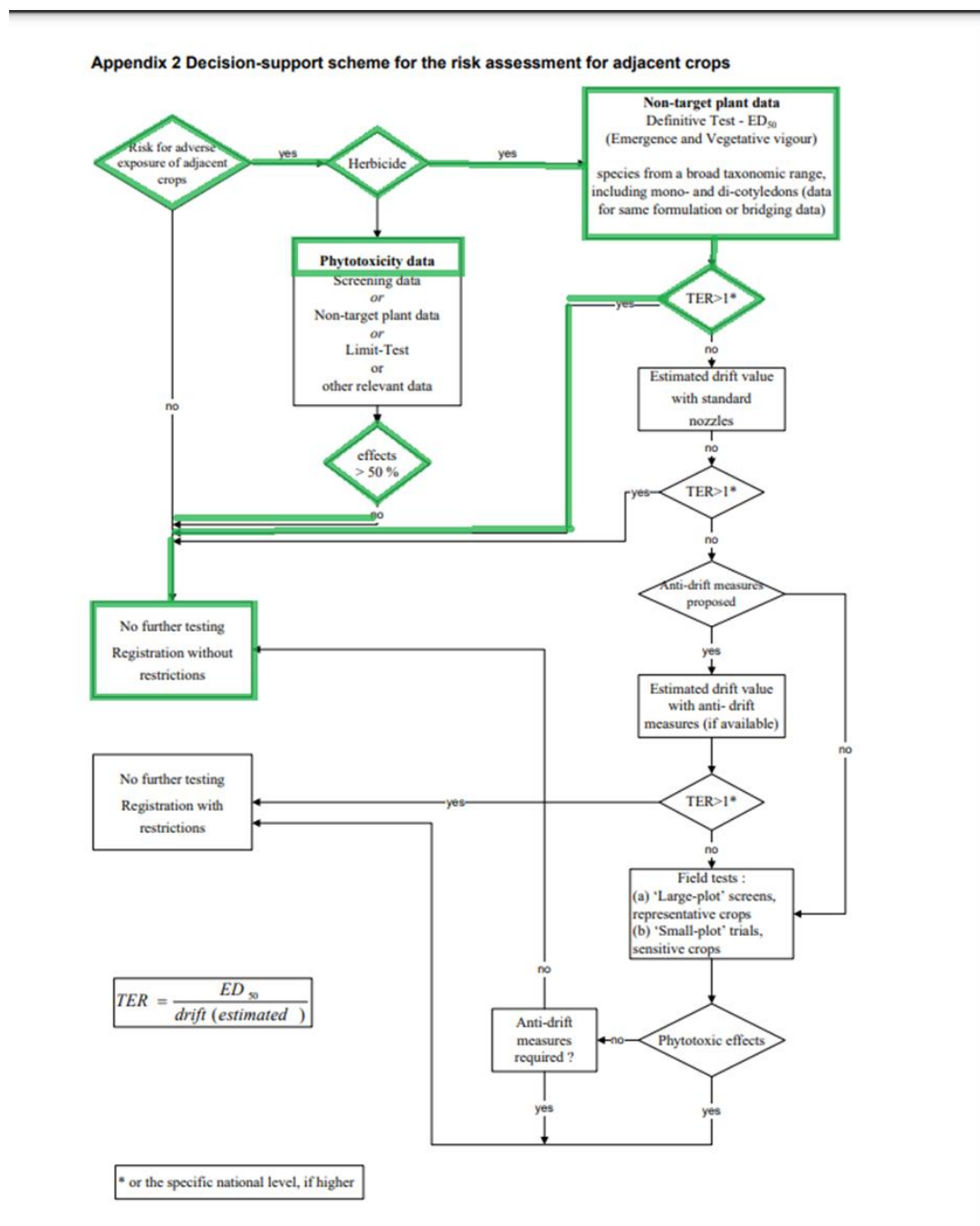
Tier 0: If no adverse exposure of adjacent crops will occur under field conditions (e.g. seed treatment, use of granules, application by watering can) no further testing is necessary.

Tier 1: If a relevant exposure is likely. If the plant protection product causes no phytotoxic symptoms on the plant species tested, no further testing is necessary.

Tier 2: If phytotoxicity is observed, dose-response relationships for species representing plant families for which significant negative activity has been found should be generated to quantify the level of effect using both soil and foliar exposure scenarios.

MEZI 100 SC analyse for decision if further testing is necessary.

According EPPO 1/256, Appendix 2 Decision-support scheme for the risk assessment for adjacent crops on green applicant marked path of analyse.



MEZI 100 SC is herbicide so there is risk for adverse exposure of adjacent crops. When analysing phytotoxicity MEZI 100 SC in maize there was not any phytotoxicity symptoms in all phytotoxicity trials conducted in Poland.

For all data and details with assessment of the risk for non-target plants due to the use of MEZI 100 SC please refer to section 9 Ecotoxicology point 9.10.

In all efficacy trials no effect on non-target organisms was observed.

When phytotoxicity effects are below 50% no further testing is needed. Registration without restrictions.

According to *Raport oceniający dokumentację wniosku rejestracyjnego herbicydu Callisto 100 SC w zakresie skuteczności i fitotoksyczności* in the efficacy and selectivity trials carried out with Callisto 100 SC there was no risk to adjacent crops.

dRR point 3.5.2	ZRMS conclusion
At a maximum application rate of 1,0 l/ha: according to the label of the reference product, in order to protect non-target plants, it is necessary to demarcate a buffer zone of: - 20 m or - 10 m and use a drift reduction nozzle of 50% or - 1 m and use a drift reduction nozzle of 75%	

### Tank cleaning

The Applicant has not carried out tests in this field.

dRR point Tank cleaning	ZRMS conclusion
In the opinion of ZRMS normal procedures should be followed for the cleaning and use of protective clothing and equipment.	

### 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

### Summary and conclusion

Herbicide MEZI 100 SC has demonstrated good crop tolerance to maize. Therefore concluded that MEZI 100 SC is safe usage at proposed rate and this support the label claim for the use in maize.

Undesirable effects are not expected on succeeding crops, adjacent crop, part of plants used for propagating purposes and beneficial organisms.

According to the above, the plant protection product MEZI 100 SC can be approved to the market and use in Poland according to proposed range of use – GAP.

Based on submitted data the following regulation on the label is proposed:

Poland

Maize:

Recommended dose at:

1.0 L/ha of MEZI 100 SC – postemergence application once a season in maize, which are corresponding to 100 g a.s./ha (mesotrione).



The product MEZI 100 SC should be use once per season at spring postemergence BBCH 14-15 in maize. To avoid resistance, products contain active substance with the same group shouldn't be used year after year on the same field.

Recommended volume of water 200-300 L/ha (maize)  
Recommended medium droplet spraying

Use of MEZI 100 SC according to the proposed GAP does not represent a hazard to rotational crops and does not justify a specific labelling. MEZI 100 SC is not persistent in soil nor is it taken up by succeeding crops.

### **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**

<b>Test facility</b>	<b>Address</b>	<b>Certificate (Yes or No)</b>
SynTech Research Poland Sp. z o.o.	ul. Jagiellońska 69/1, 85-027 Bydgoszcz, Poland	Yes

## 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	Data Vertebrate study Y/N	Owner
KCP 6.2	Eliza Potocka	2023	Efficacy and selectivity of CHR/H/MEZI (mesotrione 100 g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz, Poland Report no: <b>EU-23-1560-PL01</b> GEP – yes Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 6.2	Eliza Potocka	2023	Efficacy and selectivity of CHR/H/MEZI (mesotrione 100 g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz, Poland Report no: <b>EU-23-1560-PL02</b> GEP – yes Unpublished	N	PUH Chemirol Sp. z o.o.
KCP 6.2	Eliza Potocka	2023	Efficacy and selectivity of CHR/H/MEZI (mesotrione 100 g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz, Poland Report no: <b>EU-23-1560-PL03</b> GEP – yes Unpublished	N	PUH Chemirol Sp. z o.o.

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

Not applicable

**List of data submitted by the applicant and not relied on**

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

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

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

## **Appendix 2 Additional information provided by the applicant**

Not applicable

### Appendix 3 Summary of data on trials site and application details per use

Test report/ re-search number (1)	Trial location (2); Crop cultivar; F/G (3); N/A (4)	Testing Unit (5)	Test method (6); Plot size; Sample size (7)	Treatment			
				Growth stage (8)	Interval	Total number	Spray volume (L/ha)
<b>EU-23-1560-PL01</b>	Naglady/ Poland maize/ SM Perseus  F N	SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Poland	EPPO PP 1/50(4)  3.0 m x 4.0 = 12.0 m <sup>2</sup>	BBCH 14-16	n/a	1	200 L/ha
<b>EU-23-1560-PL02</b>	Jablowo Paluckie/ Poland maize/ SY Calo  F N	SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Poland	EPPO PP 1/50(4)  3.0 m x 5.0 = 15.0 m <sup>2</sup>	BBCH 14-15	n/a	1	300 L/ha
<b>EU-23-1560-PL03</b>	Gaj Mały/ Poland maize/ Opoka  F N	SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Poland	EPPO PP 1/50(4)  3.0 m x 5.0 = 15.0 m <sup>2</sup>	BBCH 14-15	n/a	1	200 L/ha

**Notes:**

- (1): test report number including the year of establishing the trial
- (2): precise place of the trial followed by the country
- (3): F= field trial, G=protected crop, specify
- (4): N=Natural infestation, A= Artificial inoculation
- (5): Trial responsible entity/ officially recognized organization
- (6): Test guideline used
- (7): Sample size per plot
- (8): Crop growth stage at application timing

#### Appendix 4 Summary of data on effectiveness trials per use

Test report (1)	Crop/ cultivar Harmful organ- ism/ weed species or intended use	Assessed part and variable (2)  no / m²	Untreated  BBCH (during appli- cation)	Efficacy treatments (3)				Remarks (4)
				Product		Standard (s)		
				name	Dose [L,kg//ha]	name	dose [L/ha]	
EU-23-1560-PL01	maize/ SM Perseus  CHEAL ECHCG POLCO POLPE GAETE	CHEAL 10.57 ECHCG 69.28 POLCO 7.0 POLPE 6.0 GAETE 5.43	CHEAL BBCH 12-35 ECHCG BBCH 12-23 POLCO BBCH 12-18 POLPE BBCH 12-18 GEATE BBCH 12-21	MEZI 100 SC	1.0 L/ha	Callisto 100 SC	1.0 L/ha	Application date: 22.06.2023 Assessment date: 22.06.2023 29.06.2023 06.07.2023 19.07.2023
EU-23-1560-PL02	maize/ SY Calo  ECHCG CHEAL POLCO POLPE GASPA CAPBP	ECHCG 11.0 CHEAL 27.0 POLCO 9.0 POLPE 7.0 GASPA 10.0 CAPBP 8.0	ECHCG BBCH 12-13 CHEAL BBCH 14-15 POLCO BBCH 13-15 POLPE BBCH 14-15 GASPA BBCH 13-14 CAPBP BBCH 13-15	MEZI 100 SC	1.0 L/ha	Callisto 100 SC	1.0 L/ha	Application date: 20.06.2023 Assessment date: 20.06.2023 27.06.2023 04.07.2023 18.07.2023
EU-23-1560-PL03	maize/ Opoka  ECHCG CHEAL POLCO CAPBP SETPU	ECHCG 8.0 CHEAL 12.1 POLCO 5.6 CAPBP 5.3 SETPU 20.9	ECHCG BBCH 12-16 CHEAL BBCH 13-21 POLCO BBCH 14-21 CAPBP BBCH 13-22 SETPU BBCH 13-21	MEZI 100 SC	1.0 L/ha	Callisto 100 SC	1.0 L/ha	Application date: 09.06.2023 Assessment date: 09.06.2023 15.06.2023 22.06.2023 06.07.2023

**Notes:**

- 1): Test report number including the year of establishing the trial  
(2): Plant part assessed and criteria for assessment  
(3): efficacy or intended effect  
(4): Relevant conclusions on effectiveness

## Appendix 5 Summary of detailed data on herbicide effectiveness trials

*Table 1. The efficacy of MEZI 100 SC in control of CHEAL 14 DA-A*

Pest code			CHEAL					
Report code			EU-23-1560-PL01	EU-23-1560-PL02	EU-23-1560-PL03			
Application date			22.06.2023	20.06.2023	09.06.2023			
Crop stage in application			BBCH 14-16	BBCH 14-15	BBCH 14-15			
Pest stage			BBCH 12-35	BBCH 14-15	BBCH 13-21			
Assessment date			06.07.2023	04.07.2023	22.06.2023			
Days after application DA-A			14 DA-A	14 DA-A	13 DA-A	Average	Min.	Max.
weeds density pcs/m <sup>2</sup>			11.9	27.0	12.1	17.0	11.9	27.0
No.	Name	Rate (L, kg/ha)						
1	Untreated Check	-	0.00	0.00	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	98.70	81.40	82.90	87.67	81.40	98.70
3	Callisto 100 SC	1.0	98.90	87.90	84.40	90.40	84.40	98.90
LSD(P=.05)			1.350	3.480	3.040			

*Table 2. The efficacy of MEZI 100 SC in control of CHEAL 28 DA-A*

Pest code			CHEAL					
Report code			EU-23-1560-PL01	EU-23-1560-PL02	EU-23-1560-PL03			
Application date			22.06.2023	20.06.2023	09.06.2023			
Crop stage in application			BBCH 14-16	BBCH 14-15	BBCH 14-15			
Pest stage			BBCH 12-35	BBCH 14-15	BBCH 13-21			
Assessment date			19.07.2023	18.07.2023	06.07.2023			
Days after application DA-A			27 DA-A	28 DA-A	27 DA-A	Average	Min.	Max.
weeds density pcs/m <sup>2</sup>			69.3	27.0	12.1	36.1	12.1	69.3
No.	Name	Rate (L, kg/ha)						
1	Untreated Check	-	0.00	0.00	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	100.00	97.30	96.60	97.97	96.60	100.00
3	Callisto 100 SC	1.0	100.00	99.00	96.40	98.47	96.40	100.00
LSD(P=.05)			-	1.760	3.280			

*Table 3. The efficacy of MEZI 100 SC in control of ECHCG 14 DA-A*

Pest code			ECHCG					
Report code			EU-23-1560-PL01	EU-23-1560-PL02	EU-23-1560-PL03			
Application date			22.06.2023	20.06.2023	09.06.2023			
Crop stage in application			BBCH 14-16	BBCH 14-15	BBCH 14-15			
Pest stage			BBCH 12-23	BBCH 12-13	BBCH 12-16			
Assessment date			06.07.2023	04.07.2023	22.06.2023			
Days after application DA-A			14 DA-A	14 DA-A	13 DA-A	Average	Min.	Max.
weeds density pcs/m <sup>2</sup>			69.3	11.3	8.0	29.5	8.0	69.3
No.	Name	Rate (L, kg/ha)						
1	Untreated Check	-	0.00	0.00	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	83.60	60.00	70.00	71.20	60.00	83.60
3	Callisto 100 SC	1.0	82.90	72.90	66.40	74.07	66.40	82.90
LSD(P=.05)			3.190	3.650	7.010			

*Table 4. The efficacy of MEZI 100 SC in control of ECHCG 28 DA-A*

Pest code			ECHCG					
Report code			EU-23-1560-PL01	EU-23-1560-PL02	EU-23-1560-PL03			
Application date			22.06.2023	20.06.2023	09.06.2023			
Crop stage in application			BBCH 14-16	BBCH 14-15	BBCH 14-15			
Pest stage			BBCH 12-23	BBCH 12-13	BBCH 12-16			
Assessment date			19.07.2023	18.07.2023	06.07.2023			
Days after application DA-A			27. DA-A	28 DA-A	27 DA-A	Average	Min.	Max.
weeds density pcs/m <sup>2</sup>			69.2	11.3	8.0	29.5	8.0	69.2
No.	Name	Rate (L, kg/ha)						
1	Untreated Check	-	0.00	0.00	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	80.00	80.70	77.90	79.53	77.90	80.70
3	Callisto 100 SC	1.0	79.30	87.10	75.70	80.70	75.70	87.10
LSD(P=.05)			1.750	3.360	5.850			



*Table 5. The efficacy of MEZI 100 SC in control of POLCO 14 DA-A*

Pest code			POLCO					
Report code			EU-23-1560-PL01	EU-23-1560-PL02	EU-23-1560-PL03			
Application date			22.06.2023	20.06.2023	09.06.2023			
Crop stage in application			BBCH 14-16	BBCH 14-15	BBCH 14-15			
Pest stage			BBCH 12-18	BBCH 13-15	BBCH 14-21			
Assessment date			06.07.2023	04.07.2023	22.06.2023			
Days after application DA-A			14 DA-A	14 DA-A	13 DA-A	Average	Min.	Max.
weeds density pcs/m <sup>2</sup>			7.0	9.1	5.6	7.2	5.6	9.1
No.	Name	Rate (L, kg/ha)						
1	Untreated Check	-	0.00	0.00	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	72.10	74.30	80.00	75.47	72.10	80.00
3	Callisto 100 SC	1.0	75.00	83.60	79.30	79.30	75.00	83.60
LSD(P=.05)			3.640	3.170	4.070			

*Table 6. The efficacy of MEZI 100 SC in control of POLCO 28 DA-A*

Pest code			POLCO					
Report code			EU-23-1560-PL01	EU-23-1560-PL02	EU-23-1560-PL03			
Application date			22.06.2023	20.06.2023	09.06.2023			
Crop stage in application			BBCH 14-16	BBCH 14-15	BBCH 14-15			
Pest stage			BBCH 12-18	BBCH 13-15	BBCH 14-21			
Assessment date			19.07.2023	18.07.2023	06.07.2023			
Days after application DA-A			27. DA-A	28 DA-A	27 DA-A	Average	Min.	Max.
weeds density pcs/m <sup>2</sup>			7.0	9.1	5.6	7.2	5.6	9.1
No.	Name	Rate (L, kg/ha)						
1	Untreated Check	-	0.00	0.00	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	77.10	81.40	98.30	85.60	77.10	98.30
3	Callisto 100 SC	1.0	77.10	87.90	98.10	87.70	77.10	98.10
LSD(P=.05)			2.670	3.860	1.830			

*Table 7. The efficacy of MEZI 100 SC in control of POLPE 14 DA-A*

Pest code			POLPE				
Report code			EU-23-1560-PL01	EU-23-1560-PL02			
Application date			22.06.2023	20.06.2023			
Crop stage in application			BBCH 14-16	BBCH 14-15			
Pest stage			BBCH 12-18	BBCH 14-15			
Assessment date			06.07.2023	04.07.2023			
Days after application DA-A			14 DA-A	14 DA-A	Average	Min.	Max.
weeds density pcs/m <sup>2</sup>			6.0	7.0	6.5	6.0	7.0
No.	Name	Rate (L, kg/ha)					
1	Untreated Check	-	0.00	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	75.00	77.90	76.45	75.00	77.90
3	Callisto 100 SC	1.0	76.40	82.90	79.65	76.40	82.90
LSD(P=.05)			4.400	3.650			

*Table 8. The efficacy of MEZI 100 SC in control of POLPE 28 DA-A*

Pest code			POLPE				
Report code			EU-23-1560-PL01	EU-23-1560-PL02			
Application date			22.06.2023	20.06.2023			
Crop stage in application			BBCH 14-16	BBCH 14-15			
Pest stage			BBCH 12-18	BBCH 14-15			
Assessment date			19.07.2023	18.07.2023			
Days after application DA-A			27. DA-A	28 DA-A	Average	Min.	Max.
weeds density pcs/m <sup>2</sup>			6.0	7.0	6.5	6.0	7.0
No.	Name	Rate (L, kg/ha)					
1	Untreated Check	-	0.00	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	80.00	98.40	89.20	80.00	98.40
3	Callisto 100 SC	1.0	80.00	99.00	89.50	80.00	99.00
LSD(P=.05)			-	1.240			

*Table 9. The efficacy of MEZI 100 SC in control of GAETE 14 DA-A*

Pest code			<b>GAETE</b>			
Report code			EU-23-1560-PL01			
Application date			22.06.2023			
Crop stage in application			BBCH 14-16			
Pest stage			BBCH 12-21			
Assessment date			06.07.2023			
Days after application DA-A			14 DA-A	<b>Average</b>	<b>Min.</b>	<b>Max.</b>
weeds density pcs/m <sup>2</sup>			5.4	5.4	5.4	5.4
No.	Name	Rate (L, kg/ha)				
1	Untreated Check	-	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	84.30	84.30	84.30	84.30
3	Callisto 100 SC	1.0	84.30	84.30	84.30	84.30
LSD(P=.05)			2.670			

*Table 10. The efficacy of MEZI 100 SC in control of GAETE 28 DA-A*

Pest code			<b>GAETE</b>			
Report code			EU-23-1560-PL01			
Application date			22.06.2023			
Crop stage in application			BBCH 14-16			
Pest stage			BBCH 12-21			
Assessment date			19.07.2023			
Days after application DA-A			27. DA-A	<b>Average</b>	<b>Min.</b>	<b>Max.</b>
weeds density pcs/m <sup>2</sup>			5.4	5.4	5.4	5.4
No.	Name	Rate (L, kg/ha)				
1	Untreated Check	-	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	100.00	100.00	100.00	100.00
3	Callisto 100 SC	1.0	100.00	100.00	100.00	100.00
LSD(P=.05)			-			

*Table 11. The efficacy of MEZI 100 SC in control of GASPA 14 DA-A*

Pest code			<b>GASPA</b>			
Report code			EU-23-1560-PL02			
Application date			20.06.2023			
Crop stage in application			BBCH 14-15			
Pest stage			BBCH 13-14			
Assessment date			04.07.2023			
Days after application DA-A			14 DA-A	<b>Average</b>	<b>Min.</b>	<b>Max.</b>
weeds density pcs/m <sup>2</sup>			10.0	10.0	10.0	10.0
No.	Name	Rate (L, kg/ha)				
1	Untreated Check	-	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	85.00	85.00	85.00	85.00
3	Callisto 100 SC	1.0	88.60	88.60	88.60	88.60
LSD(P=.05)			3.110			

*Table 12. The efficacy of MEZI 100 SC in control of GASPA 28 DA-A*

Pest code			<b>GASPA</b>			
Report code			EU-23-1560-PL02			
Application date			20.06.2023			
Crop stage in application			BBCH 14-15			
Pest stage			BBCH 13-14			
Assessment date			18.07.2023			
Days after application DA-A			28 DA-A	<b>Average</b>	<b>Min.</b>	<b>Max.</b>
weeds density pcs/m <sup>2</sup>			10.0	10.0	10.0	10.0
No.	Name	Rate (L, kg/ha)				
1	Untreated Check	-	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	99.00	99.00	99.00	99.00
3	Callisto 100 SC	1.0	99.00	99.00	99.00	99.00
LSD(P=.05)			-			

*Table 13. The efficacy of MEZI 100 SC in control of CAPBP 14 DA-A*

Pest code			CAPBP				
Report code			EU-23-1560-PL02	EU-23-1560-PL03			
Application date			20.06.2023	09.06.2023			
Crop stage in application			BBCH 14-15	BBCH 14-15			
Pest stage			BBCH 13-15	BBCH 13-22			
Assessment date			04.07.2023	22.06.2023			
Days after application DA-A			14 DA-A	13 DA-A	Average	Min.	Max.
weeds density pcs/m <sup>2</sup>			8.0	5.3	6.7	5.3	8.0
No.	Name	Rate (L, kg/ha)					
1	Untreated Check	-	0.00	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	87.90	80.00	83.95	80.00	87.90
3	Callisto 100 SC	1.0	89.30	77.90	83.60	77.90	89.30
LSD(P=.05)			2.380	3.240			

*Table 14. The efficacy of MEZI 100 SC in control of CAPBP 28 DA-A*

Pest code			CAPBP				
Report code			EU-23-1560-PL02	EU-23-1560-PL03			
Application date			20.06.2023	09.06.2023			
Crop stage in application			BBCH 14-15	BBCH 14-15			
Pest stage			BBCH 13-15	BBCH 13-22			
Assessment date			18.07.2023	06.07.2023			
Days after application DA-A			28 DA-A	27 DA-A	Average	Min.	Max.
weeds density pcs/m <sup>2</sup>			8.0	5.3	6.7	5.3	8.0
No.	Name	Rate (L, kg/ha)					
1	Untreated Check	-	0.00	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	99.00	94.30	96.65	94.30	99.00
3	Callisto 100 SC	1.0	99.00	92.90	95.95	92.90	99.00
LSD(P=.05)			-	2.910			

*Table 15. The efficacy of MEZI 100 SC in control of SETPU 14 DA-A*

Pest code			<b>SETPU</b>			
Report code			EU-23-1560-PL03			
Application date			09.06.2023			
Crop stage in application			BBCH 14-15			
Pest stage			BBCH 13-21			
Assessment date			22.06.2023			
Days after application DA-A			13 DA-A	<b>Average</b>	<b>Min.</b>	<b>Max.</b>
weeds density pcs/m <sup>2</sup>			20.9	20.9	20.9	20.9
No.	Name	Rate (L, kg/ha)				
1	Untreated Check	-	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	0.00	0.00	0.00	0.00
3	Callisto 100 SC	1.0	0.00	0.00	0.00	0.00
LSD(P=.05)			-			

*Table 16. The efficacy of MEZI 100 SC in control of SETPU 28 DA-A*

Pest code			<b>SETPU</b>			
Report code			EU-23-1560-PL03			
Application date			09.06.2023			
Crop stage in application			BBCH 14-15			
Pest stage			BBCH 13-21			
Assessment date			06.07.2023			
Days after application DA-A			27 DA-A	<b>Average</b>	<b>Min.</b>	<b>Max.</b>
weeds density pcs/m <sup>2</sup>			20.9	20.9	20.9	20.9
No.	Name	Rate (L, kg/ha)				
1	Untreated Check	-	0.00	0.00	0.00	0.00
2	MEZI 100 SC	1.0	0.00	0.00	0.00	0.00
3	Callisto 100 SC	1.0	0.00	0.00	0.00	0.00
LSD(P=.05)			-			

## Appendix 6 Summary of phytotoxicity trials data in summary form

Table 1 – data from phytotoxicity trials – maize (selectivity trials)

Report code	Treatment	Dose [L/ha]	Phytotoxicity in %		
EU-23-1560-PL01	Timing of assessment date	DA-A	7 DA-A	14 DA-A	27 DA-A
			29.06.2023	06.07.2023	19.07.2023
	Untreated Check	-	0.00	0.00	0.00
	MEZI 100 SC	1.0	0.00	0.00	0.00
	Callisto 100 SC	1.0	0.00	0.00	0.00
	LSD (P=0.05)		-	-	-
EU-23-1560-PL02	Timing of assessment date	DA-A	7 DA-A	14 DA-A	28 DA-A
			27.06.2023	04.07.2023	18.07.2023
	Untreated Check	-	0.00	0.00	0.00
	MEZI 100 SC	1.0	0.00	0.00	0.00
	Callisto 100 SC	1.0	0.00	0.00	0.00
	LSD (P=0.05)		-	-	-
EU-23-1560-PL03	Timing of assessment date	DA-A	6 DA-A	13 DA-A	27 DA-A
			15.06.2023	22.06.2023	06.07.2023
	Untreated Check	-	0.00	0.00	0.00
	MEZI 100 SC	1.0	0.00	0.00	0.00
	Callisto 100 SC	1.0	0.00	0.00	0.00
	LSD (P=0.05)		-	-	-

Table 2 – data from phytotoxicity trials

Test report (1)	Testing Unit GEP (2)	Country Re- gion (3)	Dates of trials and GS (4)	Cultivar F/G (5) N/A (6)	Experimental de- sign Test method (7) Replicates	Remarks
<b>EU-23-1560-PL01</b>	SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Poland	Naglady/ Poland	22.06.2023 BBCH 14-16	maize/ SM Perseus  F N	Randomized blocks EPPO PP 1/135 (4) 7	Soil type: loamy sand pH 5.3
<b>EU-23-1560-PL02</b>	SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Poland	Jablowo Paluc- kie/ Poland	20.06.2023 BBCH 14-15	maize/ SY Calo  F N	Randomized blocks EPPO PP 1/135 (4) 7	Soil type: sandy clay- loam pH 6.5
<b>EU-23-1560-PL03</b>	SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Poland	Gaj Mały/ Po- land	09.06.2023 BBCH 14-15	maize/ Opoka  F N	Randomized blocks EPPO PP 1/135 (4) 7	Soil type: sandy loam pH 5.8

Notes:

(1): test report number

(2): Trial responsible entity/ officially recognized organization

(3): precise place of the trial followed by the country

(4): Crop growth stage at application timing

(5): F= field trial, G=protected crop, specify

(6): N=Natural infestation, A= Artificial inoculation

(7): Test guideline used



## **Appendix 7 Summary of available studies: Adverse effects on beneficial organisms**

None

## **Appendix 8 Summary of data on succeeding crop**

None