

# FINAL REGISTRATION REPORT

## Part A

### Risk Management

Product code: MEZ-HER 100 SC

Product name(s): MECORN 100 SC

Chemical active substance:

mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

(authorization)

Applicant: Pestila Sp. z o. o.

Submission date: October 2023

MS Finalisation date: May 2024, August 2024; December 2025

## Version history

When	What
October 2023	Applicant submission
May 2024	Initial assessment by the zRMS
August 2024	ZRMs added some information's during commenting period
December 2025	Lists of data considered for national authorization has been updated

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# PART A

## RISK MANAGEMENT

### 1 Details of the application

#### 1.1 Application background

This application was submitted by Pestila Spółka z ograniczoną odpowiedzialnością (hereinafter referred as Pestila Sp. z o. o.)

The application for registration plant protection product under product code MEZ-HER 100 SC was submitted according to Article 33 and Article 34 of Regulation 1107/2009 and is based on data for which a 10-year protection period has expired (acc. Art. 34 of Reg. 1107/2009). MEZ-HER 100 SC is a suspension concentrate, containing 100 g/L of mesotrione to be used as an herbicide to protect maize.

#### 1.2 Letters of Access

Letter of Access was separately submitted.

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

Author	Year	Title Report number Source GLP Published	Justification for submitting
Section 1: Identity			
Section 2: Physical and chemical properties,			
Section 4: Further information			
Mazzei A.	2023	Determination of Explosive Properties on the Sample MEZ-2304703 Innovhub – Stazioni Sperimentali per l’Industria S.r.l. GLP Published: No	Regarding Commission Regulation (EU) No. 284/2013 of 1st of March 2013 it was assess that in case when the new recipe of the generic plant protection product is developed it is necessary to generate physical and chemical properties in order to check if it fulfils FAO specification, is safe, stable etc. The range of studies performed for MEZ-HER 100 SC are those recommended for SC formulation.
Digrandi S.	2023	Determination of the Physical-Chemical properties of MEZ-HER 100 SC. Product Before and after Accelerated Storage for 14 days at 54±2 °C and low temperature storage for 7 days at 0±2°C. Report No 23214-02C Renolab S.r.l. GLP Published: No	
Section 3: Efficacy Data and Information			
Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_340 GEP: Yes	In accordance with the requirements of Commission Regulation (EU) No. 284/2013 of 1st of March 2013 “ <i>The data supplied must be sufficient to permit an evaluation of the plant protection product to be made.</i> ” Formulation of Diflufenikan 500 SC was not

		Published: No	evaluated, so it was necessary to confirm efficacy and selectivity.
Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_341 GEP: Yes Published: No	
Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_343 GEP: Yes Published: No	
Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_344 GEP: Yes Published: No	
Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_345 GEP: Yes Published: No	
Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_346 GEP: Yes Published: No	
Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in silage maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_347 GEP: Yes Published: No	
Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in grain maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_348 GEP: Yes Published: No	
Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in silage maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_349 GEP: Yes Published: No	
Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in grain maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_350 GEP: Yes Published: No	

Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in silage maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_351 GEP: Yes Published: No	
<b>Section 5: Analytical Methods</b>			
Digrandi S.	2023	Analytical Method Validation for Active Ingredient and impurities Content Determination of the MEZ-HER 100 SC Report No 23214-01C Renolab S.r.l. GLP: Yes Published: No	Regarding Regulation 284/2013 of 1 <sup>st</sup> of March 2013 it was assess that in case when the new recipe of the generic plant protection product is developed it is necessary to generate analytical methods for determination of active substances and relevant impurities in the formulation in order to check if it fulfils FAO specification, is safe, stable etc.
<b>Section 8: Environmental Fate</b>			
Hara-Skrzypiec A.	2023	MEZ-HER 100 SC- calculation of Predicted Environmental Concentrations of mesotrione and its metabolites in ground water using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models. Company Report No: EST/18/2023 Source: ESTICON Sp. z o.o., Poland GEP: No Published: No	Modelling of PECgw according to EU and national requirements is always required.

## 1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

## 2 Details of the authorization decision

### 2.1 Product identity

Product code	MEZ-HER 100 SC
Product name in MS	Please refer to the cover letter.
Authorization number	Not applicable.
Function	Herbicide.
Applicant	Pestila Sp. z o. o.
Active substance(s) (incl. content)	Mesotrione 100 g/L
Formulation type	Suspension concentrate [SC]
Packaging	250mL, 0.5L, 1L,5L, 10L, 20L bottles, cannisters HDPE, HDPE/PA (COEX), fHDPE and 220L, 1000L drums and containers HDPE professional

Coformulants of concern for national authorizations	Not applicable.
Restrictions related to identity	Not applicable.
Mandatory tank mixtures	Not applicable.
Recommended tank mixtures	Not applicable.

## 2.2 Conclusion

Mecorn 100 SC (product code: MEZ-HER 100 SC) can be granted in Poland in line to accepted GAP table and label project.

## 2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.

## 2.4 Classification and labelling

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

Hazard class(es), categories:	<b>Eye Irrit. 2</b> <b>Repr. 2, H361d</b> <b>Aquatic Acute 1, H400</b> <b>Aquatic Chronic 1, H410</b>
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	<b>GHS08 GHS07 GHS09</b>
Signal word:	<b>Warning</b>
Hazard statement(s):	<b>H319 - Causes serious eye irritation.</b> <b>H361d - Suspected of damaging the unborn child.</b> <b>H400 - Very toxic to aquatic life.</b> <b>H410 - Very toxic to aquatic life with long lasting effects.</b>
Precautionary statement(s):	<b>WARNING SECTION OF THE LABEL (first page):</b> P202: Do not handle until all safety precautions have been read and understood. P280: Wear protective gloves and eye /face protection. P305+P351+P338-IF IN EYES: Rinse continuously with water for several minutes. Remove contacts lenses if present and easy to do, continue rinsing. P308+P313: IF exposed or concerned: Call a POISON CENTER/doctor.  Other section of the label: P270: Do not eat, drink or smoke when using this product.. P405: Store locked up.



	<p>P501: Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for triple rinsed empty clean containers which can be disposed of as non-hazardous waste.</p> <p>And P280 as follows:</p> <p><b>OPERATOR</b>  <i>„Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu”</i>  “Wear protective gloves, eye/face protection and work wear (coverall) during mixing/loading and protective gloves and work wear during application”.</p> <p>Section “First Aid”  P305+P351+P338-IF IN EYES: Rinse continuously with water for several minutes. Remove contacts lenses if present and easy to do, continue rinsing.  P308+P313: IF exposed or concerned: Call a POISON CENTER/doctor.</p>
Additional labelling phrases:	<b>EUH401</b> - To avoid risks to human health and the environment, comply with the instructions for use.

Special rule for labelling of plant protection product (PPP):

-	-
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

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

SPe 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 3	<p>For authorised application rate (1.0 L/ha) in order to protect non-target terrestrial plants, respect:</p> <ul style="list-style-type: none"> <li>an unsprayed buffer zone of 20 m to non-agricultural land, or</li> <li>an unsprayed buffer zone of 10 m to non-agricultural land combined with the spray-drift reduction by 50%, or</li> </ul> <p>reduction of the spray-drift by 75%.</p>

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

Not relevant.

## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	Exposure: None

	Classification: eye/face protection and work wear (coverall) Recommended: protective gloves.
Worker protection:	
-	No PPE. Workwear.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SPe 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 3	For authorised application rate (1.0 L/ha) in order to protect non-target terrestrial plants, respect: <ul style="list-style-type: none"> <li>• an unsprayed buffer zone of 20 m to non-agricultural land, or</li> <li>• an unsprayed buffer zone of 10 m to non-agricultural land combined with the spray-drift reduction by 50%, or</li> </ul> reduction of the spray-drift by 75%.
Other specific restrictions	
-	-

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

Integrated pest management (IPM)/sustainable use:	
-	-

## 2.5.2 Specific restrictions linked to the intended uses

Not relevant.

## 2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): MEZ-HER 100 SC  
Active substance 1: mesotrione  
Safener: n.a.  
Synergist: n.a.  
Applicant: Pestila Sp. z o.o.  
Zone(s): Central Zone <sup>(d)</sup>  
Verified by MS: no

Formulation type: SC <sup>(a, b)</sup>  
Conc. of as 1: 100 g/l <sup>(c)</sup>  
Conc. of safener: n.a. <sup>(c)</sup>  
Conc. of synergist: n.a. <sup>(c)</sup>  
Professional use: ☒  
Non professional use: ☐

GAP rev.1, date: 2023-10-01

Field of use: Herbicide

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 destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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	Poland	Maize	F	<b>1 L/ha susceptible</b> <del>Pigweed <i>Amaranthus retroflexus</i></del> <del>AMARE;</del> <del>Field chamomile <i>Anthemis arven-</i></del> <del>sis</del> <del>ANTAR;</del> <b>Shepherd's purse</b> <i>Capsella bursa-</i> <i>pastoris</i> CAPBP; <del>Fat hen <i>Chenopodium album</i></del> <del>CHEAL;</del> <del>Common barnyard grass <i>Echi-</i></del> <del><i>nochloa crus-galli</i></del> <del>ECHCG;</del> <b>Cleavers</b> <i>Galium aparine</i> GALAP; <del>Gallant soldier <i>Galinsoga parvi-</i></del> <del><i>flora</i></del> <del>GASPA;</del> <b>Purple deadnettle</b> <i>Lamium pur-</i> <i>pureum</i> LAMPU; <del>Wild buckwheat <i>Fallopia convol-</i></del> <del><i>ulus</i></del> <del>POLCO;</del>	broadcast spraying	BBCH 14-15 Spring, post emergence	1 a) 1 b) 1	N/A	1 L/ha a) 1 L/ha b) 1 L/ha	100g mesotrione a) 100g mesotri- one b) 100g mesotri- one	200- 300 L/ha	not relevant	not relevant  <b>Efficacy section:</b> List of accepted weed species and their sensitivity was changed.

			<b>Common chickweed</b> <i>Stellaria media</i> STEME; <b>Fanweed</b> <i>Thlaspi arvense</i> THLAR; <b>Field pansy</b> <i>Viola arvensis</i> VI-OAR  <u><b>1L/ha Moderately susceptible</b></u> <del>Common fumitory</del> <i>Fumaria officinalis</i> FUMOF <b>Fat-hen</b> <i>Chenopodium album</i> CHEAL; <b>Common barnyard grass</b> <i>Echinochloa crus-galli</i> ECHCG; <b>Volunteer rape seedlings</b> <del>BRSNN</del> <i>Brassica napus</i>										
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**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.

**Remarks columns:**

1 Numeration necessary to allow references  
2 Use official codes/nomenclatures of EU Member States  
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  
8 The maximum number of application possible under practical conditions of use must be provided.  
9 Minimum interval (in days) between applications of the same product  
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".  
13 PHI - minimum pre-harvest interval  
14 Remarks may include: Extent of use/economic importance/restrictions

### 3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that homogenous sand colour suspension liquid. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 443 °C. In aqueous solution, it has a pH value around 3.46 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient as well as relevant impurities content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.33% to 0.5%.

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

#### 3.3 Efficacy data

The application for registration of a plant protection product under working name MEZ-HER 100 SC according to Article 33 based on Article 34 of Regulation 1107/2009. MEZ HER 100 SC is a suspension concentrate formulation (SC), containing 100 g/kg of mesotrione to be used as a herbicide to protect maize.

The reference product to the product under the code MEZ-HER 100 SC is Callisto 100 SC, that has been first registered in Poland according to authorisation Minister of Agricultural and Rural Development No. R-25/2009 of 27.02.2009 which means, that data protection, for the data presented by Callisto 100 SC authorisation holder, for purposes of registration, has been expired.

In respect to the above and taking into account Polish requirements for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009 applicant provides bridging, efficacy trials, to confirm that properties of MEZ-HER 100 SC are comparable to properties Callisto 100 SC in protection against weeds in maize.

Mesotrione is a selective herbicide commonly used to control broadleaf weeds and certain grasses in various crops such as maize, soybeans, turfgrass, and ornamental plants. Mesotrione inhibits the enzyme 4-hydroxyphenylpyruvate dioxygenase (HPPD), which is essential for chlorophyll biosynthesis in plants. The disruption of chlorophyll production leads to bleaching and death of susceptible weeds. Mesotrione is selective, meaning it primarily targets broadleaf weeds while having minimal impact on grass species like corn and turfgrass when used according to label instructions. The selectivity allows for effective weeds control without significant damage to the desired crop.

**Preliminary tests:** Mesotrione was first introduced in the early 2000s. Mesotrione received regulatory approval for use in various crops, including corn, turfgrass and certain vegetables, and has been used in agriculture since then.




In Poland, 58 PPPs with mesotrione as an active compound are registered and commonly used in Poland on the basis on the Ministry Register of Plant protection products, dated 30.04.2024. So, the active substance of Mecorn 100 SC (product code: MEZ-HER 100 SC) – Mesotrione is registered and have been commonly used in agricultural practice for many years. Large scale efficacy trials are available to evaluate the effectiveness of products containing this active compound. So, no primary and screening tests are required.

**Minimum Effective dose:** To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least on lower dose(s). For example, 60-80% of the recommended dose should be used during field trials, to that would be recommended. It is utilized to achieve the desired effect. During efficacy field trials Applicant used different doses of Mecorn 100 SC. So, separated MED dose were not presented in the documentation. However, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in line to EPPO 1/225 (2).

Efficacy was tested under a range of environmental conditions to full challenge the product. All trials were carried out only in one EPPO zone in Poland in one growing season. Following doses were studied during trials: 0.6 L/ha (0.6N); 1.0 L/ha (N recommended) and 1.5 L/ha (1.5N). All trials were characterized by acceptable level of infestation.

#### **Results for MED (Minimum Effective Dose):**

Weed species	No. trials	Infestation	Eff. at dose 0.6 L/ha	Eff. at dose 1.0 L/ha	Eff. at dose 1.5 L/ha
AMARE	2	6.9	73.1	83.0	90.4
BRSNW	2	5.8	75.7	80.0	91.9
CAPBP	2	5.8	70.6	85.8	92.5
CHEAL	6	7.8	69.2	84.6	93.7
ECHCG	6	5.8	71.5	84.4	91.7
GALAP	2	6.4	77.5	85.0	94.4
GASPA	1	8.8	72.5	85.3	91.0
MATIN	1	5.0	90.0	93.8	94.8
POLCO	3	7.5	61.7	77.1	92.3
STEME	2	7.3	72.5	87.1	95.6
THLAR	4	6.3	70.3	85.4	94.1
VIOAR	4	5.5	74.1	85.3	92.4

S 85-100%  MS 70-84.9%  MT 60-69.9%  T < 60% 

On the basis on obtained results it has been noted that:

- ✓ **for dose 0.6 L/ha** – 2 weeds were classified as a moderately tolerant (CHEAL, POLCO), 9 weeds as moderately susceptible (AMARE, BRSNW, CAPBP, ECHCG, GALAP, GASPA, STEME, THLAR, VIOAR) and one weed was characterized by susceptible (MATIN), Lack of weeds tolerant against Mecorn 100 SC.
- ✓ **for dose 1.0 L/ha** – lack of weeds tolerant and moderately tolerant. 5 weeds were characterized by moderately susceptible (AMARE,, BRSNW, CHEAL ECHCG, POLCO) and 7 weeds as a susceptible (CAPBP, GALAP, GASPA, MATIN, STEME, THLAR, VIOAR).
- ✓ **for dose 1.5 L/ha** – all studied weeds were characterized as a susceptible (AMARE, BRSNW, VAPBP, CHEAL, ECHCG, GALAP, GASPA, MATIN, POLCO, STEME, THLAR, VIOAR).

In the opinion of ZRMs, on the basis on results presented above it can be concluded that dose 1.5 L/ha was characterized by the best efficacy. However, dose 1.0 L/ha was also characterized by good level of efficacy. So, in the opinion of ZRMs **dose 1.0 L/ha can be recommended for use in line to proposal of Applicant in GAP and label project and submitted documentation.**

**Efficacy:** All details about efficacy methodology used during efficacy trials (in total 6) were presented above by Applicant. Submitted reports were from field trials carried out on maize in PL (N-E). Trials include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying, etc.

Applicant properly presented efficacy trials. Only trials with greater than 4-5 weeds/m<sup>2</sup> should be taken

for assessment. According to EPPO 1/226 at least 6 fully supportive results for major weeds and 2 trials for minor weeds should be required. Therefore, based on knowledge of major/minor status of weeds, weeds with insufficient results should be excluded. In Poland, 58 PPPs with Mesotrione are registered and commonly used for protect crops against weeds. So, in line to Polish rules for major weeds- at least 4 trials are required and for minor – at least 2.

Applicant would like to register Mecorn 100 SC in line to Article 33 and 34 with using unprotected data of Callisto 100 SC. In line to Polish rules, Applicant should present bridging trials in which Callisto as a st. ref. product and tested product – Mecorn 100 SC should be tested at the same time in the same field trial. However, in submitted trials other PPP as a st. reference product was used (Maisot 100 SC not Callisto 100 SC). So, registration in line to Article 34 is not possible now. Only conditionally registration could be considered as a dRR was submitted by Applicant before 1<sup>st</sup> January within 2 years after registration for submitting full package of bridging trials. However, ZRMs proposed registration of tested product – Mecorn 100 SC only in line to Article 33 on the basis on 6 trials submitted. ZRMs accepted Conducting trials only in one growing season as many PPPs with mesotrione are registered and used in PL for protect maize against weeds. Applicant presented eff. results from Callisto in the table Table 3.2-18. However, those results are from unprotected dRR from 2008 not from field trials submitted for assessing now. As, no valid bridging trials were presented, ZRMs not assessed results from Callisto and not consider in evaluation of Mecorn 100 SC. The Applicant explained that they did not conduct research on Callisto 100 SC because it was unavailable in 2022. However, according to information on the manufacturer's website and in the registry of plant protection products, Callisto 100 SC is permitted until 2033, and its sales deadline is set for 2034. Also, the list of plant protection products authorized for sale and use in 2022 in Poland included Callisto 100 SC (code: II.83 for herbicides).

Applicant submitted enough number of trials for Mecorn 100 SC (6) for registration in line to Article 33. Accepted weed species for PL should be presented to following scale of sensitivity:

- S (susceptible) >85%
- MS (moderately susceptible) 70-85%
- MT (moderately tolerant) 60-70%
- T (tolerant) <60%.

All studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by Chief inspector of Plant health and Seed Inspection and are officially GEP recognized.

All trials had 4 replicates, a randomized block design and a valid plot size (21m<sup>2</sup>) was used. Water volumes of 200 L/ha were tested, which not encompasses the full range proposed in the GAP table (200-300 L/ha). In the opinion of ZRMs recommended water volume can be 200-300 L/ha as in line to protection programs for Mesotrione and in line to registered uses of st. ref. product used during trials (Maisot 100 SC). Application window BBCH 14-15 is in line to submitted documentation and trials.

In all trials Maisot 100 SC as a st. reference product was used at dose 1.5 L/ha. Tested product – Mecorn 100 SC is recommended by Applicant for use at dose 1.0 L/ha (in line to submitted GAP and label project), so Maisot 100 SC can be tested at dose 1.5 L/ha (its registration is for 0.75-1.5 L/ha). However, ZRMs accepted submitted documentation as valid for the assessment of Mecorn 100 SC.

Below, ZRMs presented results for noted efficacy during trials.

Weed	Number of trials	Level of infestation (no/m <sup>2</sup> )	Mean eff at 1.0 L/ha	Mean eff. at dose 1.5 L/ha	st. ref. product (Maisot 100 SC) at dose 1.5 L/ha
AMARE	2	6.9	83.0	90.4	90.4
BRSNW	2	5.8	80.0	91.9	92.5
CAPBP	2	5.8	85.8	92.5	92.4
CHEAL	6	7.8	84.6	93.7	94.0
ECHCG	6	5.8	84.4	91.7	92.6
GALAP	2	6.4	85.0	94.4	95.0
GASPA	1	8.8	85.3	91.0	91.0
MATIN	1	5.0	93.8	94.8	97.0
POLCO	3	7.5	77.1	92.3	90.8
STEME	2	7.3	87.1	95.6	97.3

THLAR	4	6.3	85.4	94.1	94.4
VIOAR	4	5.5	85.3	92.4	93.6

All trials were characterized by sufficient level of infestation.

Weeds represented only by one trial should be excluded from the assessment. Excluded weed species due to very limited number of trials (only one) are: GASPA and MATIN. Also, AMARE and POLCO should be excluded due to not sufficient number of trials for major weeds in maize (at least 4 trials are required).

BRSNW, CAPBP, GALAP, STEME, THLAR and VIOAR can be accepted as a minor weeds and CHEAL, ECHCG as a major weeds in maize. The most effective and mostly comparable to st. ref. product was dose 1.5 L/ha of Mecorn 100 SC. However, also dose 1.0 L/ha is efficacy against weeds so it can be recommended in line to GAP table and label project.

**Accepted list of weed species and their sensitivity for Polish label against recommended dose (1.0 L/ha) of Mecorn 100 SC:**

- ✓ *moderately susceptible weeds:* BRSNW, CHEAL, ECHCG
- ✓ *susceptible weeds:* CAPBP, GALAP, STEME, THLAR, VIOAR.

Mecorn 100 SC can be registered for use on maize cultivated on grain, bioethanol and silage. Varieties for grain, silage and bioethanol were tested during trials.

ZRMs do not agree with Applicant that data from Maisot 100 SC can be used for registration under Article 34 in exchange for Callisto 100 SC whose data have expired). The licence holder of Maisot 100 SC is Albaugh TKI d.o.o, for Callisto 100 SC – Syngenta Polska Sp. z o.o. Maisot 100 SC was registered in 2019 and its data are still protected. Also, Applicant did not present any results for comparable of phys.-chemical comparison of the two measures (Maisot 100 SC and Mecorn 100 SC, only assessment against Mecorn 100 SC and Callisto 100 SC was made). The Applicant's statement that both agents are comparable, i.e. Maisot100 SC and Callisto 100 SC, only on the basis of the content of the active substance and their label is not sufficient. What is important, Maisot 100 SC is registered for use at dose 0.75-1.5 L/ha, whilst Callisto 100 SC – 1.0-1.5 L/ha. Sensitivity of weeds from Maisot 100 SC label is presented only for dose 0.75 and 1.5 L/ha. It is not possible to compare its effectiveness for Callisto 100 SC or Mecorn 100 SC used at dose 1.0 L/ha (lack of such data). So, in the opinion of ZRMs without submitting by Applicant the comparable of phys.-chemical comparison of the two measures (Maisot 100 SC and Mecorn 100 SC) and consent of the Maisot 100 SC authorisation holder to the use of its data is not possible. Also, the both products Maisot 100 SC and Mecorn 100 SC should be used at the same dose. Whilst during trials Mecorn was studied at dose 1.0 and 1.5 L/ha and Maisot 100 SC only at dose 1.5 L/ha.

**If the Applicant has a comparison of the compositions of Maisot 100 SC and Mecorn 100 SC (optimally) or Callisto 100 SC and Maisot 100 SC (optionally) and the consent of the Maisot 100 SC authorization holder to use its data, then registration will be possible on the basis of the use of bridging studies of Maisot 100 SC, as requested by the applicant at the time of comment. Also, both products (Maisot 100 SC and Mecorn 100 SC should be used during trials at the same dose). Without mentioned above, only registration in line to Article 33 is possible with treated Maisot 100 SC as a st. ref. product, which was already done during this assessment.**

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

Resistance to mesotrione, like with many herbicides can develop in weed populations over time due to repeated use of the herbicide. When weeds are exposed to the same herbicides over and over again, the ones that have genetic variations that makes them less susceptible to the herbicide survive and reproduce, passing on their resistant traits to their offspring.

There have been documented cases of weed populations developing resistance to mesotrione, particularly in species such as waterhemp and palmer amaranth. To manage resistance, integrated weed management strategies are recommended, which may include rotating herbicides with different modes of action, using cultural practices to reduce weed pressure, and employing non-chemical methods such as crop rotation



and mechanical weed control. Additionally, utilizing herbicide mixtures or tank-mixing Mesotrione with other effective herbicides can help delay the development of resistance.

Mesotrione is a callistemone herbicide that inhibits the HPDD enzyme and introduces a new naturally selective tool into weed management programmes for use in maize.

Mesotrione provides control of the major broad-leaved weeds, and it can be used in integrated weed management programmes depending on the grower's preferred control strategy. AT post-emergence rates of 150 a.s./ha or less, Mesotrione provides naturally selective control of key species that may show triazine resistance (TR), ex. CHEAL, AMARE, SOLNI, as well as species of weed that show resistance to acetolactase synthase (ALS) inhibitors, eg. *Amaranthus sp.*

Mecorn 100 SC (product code: MEZ-HER 100 SC) containing Mesotrione (100 g/L), a potent bleaching herbicide that belonging to triketone herbicide family (HRAC Group 2). Mecorn 100 SC is a post-emergence herbicide used to control weeds in maize crops.

17 cases of resistance against mesotrione were recorded in two species (both, *Amaranthus sp.* and *Raphanus raphanistrum*). All cases were reported in USA, Canada, and Australia. No case reported in Europe yet. The active substance is therefore classified as having a low inherent risk.

Mesotrione acts by the inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase which in turn inhibits carotenoid biosynthesis. Due to its primary target site and its chemical family, in the HRAC mode of action classification, it is classified as group F2 herbicide (4-hydroxyphenyl-pyruvate-dioxygenase (4-HPPD) inhibition). In the WSSA resistance classification system, the callistemones are classified as group 27.

The mechanism for resistance in the two weed species is currently unknown. Based on the HRAC resistance classification, cross resistance should be expected to be likely between Mesotrione and other HRAC group F2 herbicides. Thus, the analysis of the risk for the development of weed resistance to Mesotrione is made under the assumption that cross resistance exists between all herbicides classified as HRAC group F2. No cross-resistance was observed between F2 herbicides in the ten cases reported from the US.

The mesotrione resistant *Amaranth* species (*Amaranthus tuberculatus* and *Amaranthus palmeri*) populations in Iowa, Illinois, Kansas and Nebraska (USA) were reported to be cross-resistant to ALS inhibitors (HRAC group B/2), Photosystem II inhibitors (HRAC group C1/5), PPO inhibitors (HRAC group E/14), Synthetic Auxins (HRAC group O/4) and/or EPSP synthase inhibitors (HRAC group G/9).

Mesotrione have been used as straight products as well as in mixtures for many years. Without any precautions, the resistance risk is unacceptable. Should resistant populations arise, control could be achieved through use of alternative products.

Good Agricultural Practices and Good Plant Protection Practices (EPPO Standard 2/1(2)) should be the followed in the weed management strategy. Uses of mixtures with herbicides with different modes of action and weed spectrum is recommended, to obtain a high degree of weed control and get rid of eventually resistant weeds in the field and prevent resistance build up.

Follow the label recommendations regarding application rate (max 1 application per year), growth stage, doses etc.

**Always follow HRAG guidelines for the prevention and managing herbicide resistant grass and broadleaved weeds.**

Mesotrione is a widely used post-emergence herbicide for maize. The toxicity of mesotrione to maize (especially sweet corn) has been widely reported, and some sweet corn varieties are highly sensitive to mesotrione, which affects subsequent plant growth periods. However, the molecular mechanisms responsible for the differences in susceptibility to mesotrione are not known.

### 3.3.2 Adverse effects on treated crops

In the evaluation process the fact that the active compound – mesotrione is used in many plant protection

products and have been commonly used in crop protection for many years were taken into consideration. The Applicant submitted in total 5 selectivity trials carried out in Poland (N-E) in one growing season. The selectivity evaluation of the herbicide is to be performed in line to listed below EPPO guidelines. The evaluation of herbicide selectivity was carried out 4-5 per season. Results were described in percent of destruction of plant for herbicides treatment compared to plant for untreated, where 0% means no phytotoxicity and 100% - complete destruction. Phytotoxicity assessment was carried out with the use of different cultivars (commonly grown varieties). Dosage N was not studied as Applicant would like to register product for use at dose 1.0 L/ha. Only dose 1.5N (1.5 L/ha) and 3N (3 L/ha) was studied during trials. St. ref. product (Maisot 100 SC) was studied at dose 1.5 L/ha and 3.0 L/ha. Experimental details and assessments methods were in line to EPPO standards. Detailed information's were presented by Applicant in B3.

Registration of Mecorn 100 SC cannot be done in line to Article 34, because in trials Callisto 100 SC which data are unprotected was not studied and compared to tested Mecorn 100 SC. As a st. ref. product Applicant used different product – Maisot 100 SC, so registration could be only in line to Article 33 as a sufficient number of selectivity trials for Mecorn 100 SC was studied.

In the opinion of ZRMs, submitted documentation is sufficient. Studied only higher doses than included in GAP and label project is acceptable by ZRMs as a worse scenario. No phytotoxicity symptoms caused by 1.5 L/ha nor 3.0 L/ha dose of MEZ-HER 100 SC were observed in any of the performed selectivity trials. Also, in the efficacy trials o phytotoxicity was observed in each of tested rates.

**Effect on the yield and its quality:** No negative relationship between MEZ-HER 100 SC rate and yield were noted during selectivity trials. Impact of Mecorn 100 SC on the yield was evaluated during selectivity trials. Summary of the data on yield can be found in the tables below. The evaluation was carried out in line to EPPO standard's. No significant differences occurred. There were no statistically significant difference between the treatment objects and untreated samples. In selectivity trials, according to the statistical analysis, ME-HER 100 SC treatments did not have any negative impact on yield and its quality, when both 1.5 L/ha and 3.0 L/ha rates were used. So, it can be concluded that no negative effect on yield is expected for recommended dose of 1.0 L/ha of Mecorn 100 SC.

Test report	Variety	Quality trait in the untreated control			Quality traits at 1N and 1.5 absolute figures and % of untreated						Quality traits at 2N and 3N absolute figures and % of untreated					
		Absolute figures (unit)			Test product (1.5 L/ha)			Standard 1 (1.5 L/ha)			Test product (3.0 L/ha)			Standard 1 (3.0 L/ha)		
		Moisture (%)	TG W (g)	Hecto-litre weight (kg)	Moisture (%)	TG W (g)	Hecto-litre weight (kg)	Moisture (%)	TG W (g)	Hecto-litre weight (kg)	Moisture (%)	TG W (g)	Hecto-litre weight (kg)	Moisture (%)	TG W (g)	Hecto-litre weight (kg)
III 6.2.1/02 (S-M-PL-2022-182_02_F22_348) Maize	DKC3 787	28.8	266.65	72.43	29.5	268.35	72.3	29.7	266.75	72.35	29.7	267.58	72.43	29.6	267.83	72.28
III 6.2.1/04 (S-M-PL-2022-182_02_F22_350) Maize	DKC3 201	27.45	280.35	69.68	27.8	279.05	70.8	27.73	281.45	71.18	27.8	275.05	71.03	28.08	273.03	71.15

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

**Effect on transformation processes:** The effect of mesotrione on transformation processes in maize primarily involves its action as a herbicide. Mesotrione inhibits the enzyme HPDD, which plays a crucial role in the synthesis of carotenoid pigments in plants. The inhibition leads to the accumulation of toxic intermediates, resulting in bleaching and necrosis of plant tissues.

In terms of transformation processes in maize, mesotrione can affect various aspects of plant growth and development. As mesotrione disrupts carotenoid synthesis, it can impair photosynthetic efficiency in maize plants, leading to reduced growth and yield. This inhibition can lead to the bleaching of plant tissues due to the accumulation of toxic intermediates, reducing chlorophyll levels and impairing photosynthesis.

Maize plants treated with mesotrione may activate stress response pathways to cope with the herbicidal

effects. This can influence the expression of genes involved in stress signalling and defence mechanisms. The herbicide's mode of action disrupts normal metabolic processes, weakening the plant's ability to respond effectively to external challenges. But, by controlling weeds, mesotrione can help minimize the spread of pests and diseases, reducing stress on maize crops and promoting healthier plant growth. Effective weed control with mesotrione can result in cleaner maize fields with fewer weed seeds contaminating harvested grain. This can improve the quality of maize grain and reduce post-harvest losses associated with weed infestations.

Mesotrione exposure can alter the balance of plant hormones, such as auxins and cytokines, which play key roles in growth regulation and development. Disruption of hormonal pathways can impact various transformation processes, including cell division, elongation, and differentiation. These alternations may disrupt normal growth and development, leading to phenotypic abnormalities and reduced crop quality.

Mesotrione induced stress can affect metabolic pathways in maize leading to changes in the synthesis and accumulation of secondary metabolites, including phytoalexins and antioxidants. These alternations on impact on the plant defence mechanism and overall physiological responses.

The effect of mesotrione on transformation processes in maize is complex and multifaceted, involving interactions with various physiological and molecular pathways. Understanding these effects is essential for optimizing treatments and mitigating potential risks to maize production and crop performance.

While mesotrione's primary function is weed control, its indirect positive impacts on transformation processes in maize highlight its role in promoting more sustainable and efficient agricultural practices. However, it is essential to use herbicide responsibly and in conjunction with integrated weed management strategies to maximize their benefits while minimizing potential negative effects on the environment and human health.

**Considering that product is applied at early stage of the crop and maize is not a typical crop used for subsequent processing, it could be agreed that no negative impact on processing is expected. The latest time of application for Mecorn 100 SC is crop growth stage BBCH 15. Since application of Mecorn 100 SC is made at an early stage in the crop's development there is no risk that the actives would be translocated to the grain. Also, the germination of maize seeds will be not negatively affected by the application of Mecorn 00 SC, in the opinion of ZRMS.**

**Effect on propagating purposes:** Mesotrione, primarily utilized as a herbicide, does not have direct positive effects on the propagating purposes of maize. Instead, its impact is primarily negative due to its herbicidal action, which target broadleaf weeds.

Mesotrione targets weeds that compete with maize for resources such as nutrients, water and sunlight. While this is beneficial for maize growth, it does not directly impact maize propagation itself. Mesotrione can persist in the soil and may impact soil microbial communities, which play a crucial role in nutrient cycling and soil fertility. Disruption of these microbial communities could indirectly affect maize propagation by altering soil health and nutrient availability. Mesotrione, like other herbicides, can have environmental impacts if not used responsibly. Runoff or leaching of mesotrione into water bodies can harm aquatic ecosystems and potentially affects the availability of water resources for irrigation, which can indirectly impact maize propagation.

Mesotrione can indirectly benefit maize propagation by controlling weeds and reducing competition. It is essential to use mesotrione responsibly and in accordance with best management practices to minimize potential adverse impacts on maize propagation and overall agricultural sustainability.

The active substance – mesotrione is commonly used for many years in many countries. No adverse effects on parts of plant used for propagating purposes were reported. No adverse effect on the yield and its quality and no phytotoxicity symptoms were recorded in the field trials. Also, no information is available pointing to presence of any limitations to using of mesotrione in seed crops of maize. In the opinion of ZRMs, the product – Mecorn 100 SC (product code: MEZ-HER 100 SC) may be used on maize.

**Impact on succeeding crops:** The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in other part of the dossier, show that significant residues of the mesotrione, its metabolites or degradation products, which have or

may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops. Therefore, the Applicant should presented the assessment of the possible effects of Mecorn 100 SC on crops grown as rotational or replacement crops, following crops treated with that product, prepared in accordance with EPPO Standard Evaluation of plant protection product.

Effects on succeeding crops (PP 1/207 (2)). This standard is intended as a general standard on the methods used to examine whether the active substance of a plant protection product can cause negative effects on crops after a crop treated with that product. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure.

**The half-life (DT<sub>50</sub>) for mesotrione in soil is short – about 16.4 days. Therefore, the impact on succeeding crops is unlikely to occur. No risk of phytotoxicity for succeeding crops is expected, in the opinion of ZRMs and lack of calculations of TER values submitted by the applicant based on ER<sub>10</sub> values coming out from “Seedling Emergence and Seedling Growth test” can be accepted.**

In the opinion of ZRMs, necessary precautions to prevent the negative impact on succeeding crops should be included in the label claim. Applicant included in the label project of Mecorn 100 SC information’s from Callisto 100 SC which data are unprotected. **Detailed assessment of impact on succeeding crops is presented in section B7.** In the opinion of ZRMs, those data can be used if both PPPs are comparable and its composition is the same. Also, if Section B7 assessed those data as still valid. So, in the opinion of ZRMs following entry can be included in the label of Mecorn 100 SC:

*“In case of the need for early termination of a plantation treated with the agent (due to damage to maize by hail, diseases, pests, or frost), maize or perennial ryegrass can be cultivated in the field. After deep plowing, besides the aforementioned plants, sorghum can also be cultivated.*

*After harvesting maize grown under normal vegetative conditions, treated with Mecorn 100 SC herbicide no later than July 1<sup>st</sup>, and after deep plowing, all crops can be sown. In the case of cultivating sensitive plants such as sugar beet, legumes, winter rapeseed, common sunflower, and vegetables, as well as early-sown winter grains, damage may occur.*

*Under extremely unfavourable conditions (sandy soils, easily drying soils with low pH (<6.0), soil with high organic matter content (>4.0%), low biological activity, exceptionally low temperatures in winter, exceptionally low soil moisture in summer and/or autumn and/or winter, overlap of sprayed surface with the preparation, excessively compacted soil, temporary whitening growth inhibition, and reduced plant density in sensitive plants (sugar beets, legumes, common sunflowers, and vegetables) may occur. Therefore, cultivating the above mentioned plants as successor crops is not recommended when the soil pH is significantly below 6.0, or if a prolonged drought period occurred after using the agent in the previous season. Deep plowing after maize cultivation and soil pH above 6.0 significantly reduce the risk of damage to these plants.”*

**Impact on adjacent plants:** The impact of an herbicide containing mesotrione on adjacent crops can vary based on several factors, including the sensitivity of the crops, application rates, timing, environmental conditions, and the herbicide formulation. Mesotrione is a selective herbicide commonly used to control weeds in maize.

During application, mesotrione can drift or overspray onto adjacent crops, especially if not applied under appropriate weather conditions or with proper equipment. Drift can lead to unintended herbicidal effects on sensitive crops, causing symptoms such as leaf discoloration, stunting, or even crop loss. Mesotrione residues in the soil may impose rotation restrictions on adjacent crops, particularly those sensitive to the herbicide or belonging to the same botanical family as the target weeds. Mesotrione applications as part of an integrated weed management strategy may have positive implications for adjacent crops by reducing weed pressure and competition. Effective weed control with mesotrione can improve resource availability for adjacent crops, potentially enhancing their growth and yield.

The impact on other plants including adjacent crops should be presented in line to EPPO 1/256. Applicant did not presented any data. No negative side effects on target or adjacent crops have been reported in the efficacy and selectivity trials or following use of Mecorn 100 SC. In conclusion, as MEZ-HER 100 SC is intended for control of mono and dicotyledonous weeds, the product may cause damages on mono (e.g.

cereals) and dicotyledonous adjacent crops if it is misused.

Based on the probabilistic risk assessment, *to protect plants and non-target arthropods from the action of the agent, it is necessary to designate a protective zone with a width of 20 meters, or 10 meters with simultaneous use of techniques reducing the drift of the working liquid during the treatment by 50%, or 1 meter with simultaneous use of techniques reducing the drift of the working liquid during the treatment by 75%.* This impact is assessed by Section of Environmental Fate and/or Ecological Section.

The information in the registration report and label warns against overlapping and drift of the spray liquid is sufficient in the opinion of ZRMs.

**Effects on beneficial and other non –target organisms:** Detailed assessment is presented in Ecotoxicology Section. However, in the opinion of ZRMs from Efficacy section – mesotrione can have direct and indirect effects on beneficial and non-target organisms in the environment. Mesotrione can be toxic to non-target organisms if they come into direct contact with the herbicide. This includes beneficial insects such as pollinators and natural enemies of pests. Direct exposure to mesotrione can lead to mortality or sub-lethal effects, such as reduced reproduction or impaired behaviour.

Mesotrione can indirectly affect non-target organisms through the food chain. Mesotrione residues in the soil can affect soil microbial communities, earthworms, and other soil-dwelling organisms. Runoff or leaching of mesotrione into water bodies can pose risk to aquatic organisms at certain concentrations, potentially leading to acute or chronic effects on aquatic ecosystems. Even sub-lethal doses of mesotrione can have sub-lethal effects on non-target organisms, affecting their behaviour, physiology, and fitness. These effects may not be immediately apparent but can have long-term implications for population dynamics and ecosystem functioning.

It is essential to consider all potential effects when using mesotrione and to implement best management practices to minimize risks to beneficial and non-target organisms in the environment.

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

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

Analytical methods for determination of mesotrione in MEZ-HER 100 SC was not evaluated as part of the EU review of mesotrione. Therefore, all relevant data are provided and are considered adequate.

The method for determination of mesotrione in MEZ-HER 100 SC formulation is based on high performance liquid chromatography (HPLC) with a DAD detector and external standard. In order to confirm method specificity, chromatograms of acetonitrile, placebo, standard and analysed sample were superimposed and compared.

The method for determination of mesotrione in MEZ-HER 100 SC fulfils acceptability criteria contained in SANCO/3030/99 rev.5, 22 March 2019 guidance and assure appropriate active substance determination in the formulation.

Determination of relevant impurities: R287432, R287431 and 1,2-Dichloroethane was fully validated. The methods for determination are specific. The validation parameters for linearity, instrument precision, limit of quantification, repeatability and accuracy are within the acceptance range. There are not any interferences between relevant impurities and other ingredients of the samples. The methods had good precision, accuracy and the linearity and fulfil requirements of SANCO/3030/99 rev.5.

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

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

- none

Note: The table *List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review* should be completed before registration

Commodity/crop	Supported/ Not supported
Maize	Supported/

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

#### 3.5.1 Acute toxicity

Not relevant for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. For the purpose of evaluation of MEZ-HER 100 SC please refer to Renewal RR for Callisto 100 SC.

The product MEZ-HER 100 SC has not been tested to identify possible toxicological hazards and decide about the classification. The results of the comparative analysis of the composition indicate that the product MEZ-HER 100 SC is similar to the reference product Callisto 100 SC according to the guideline SANCO/12638/2011. Toxicological properties of the formulation MEZ-HER 100 SC have been defined based on the composition of the product and the results of acute toxicity tests performed for the representative formulation, i.e. Callisto 100 SC. Since the *in vivo* acute toxicity tests for the representative formulation already exist, their usage for this evaluation is justified. Whenever toxicological data obtained from animal studies are available, they should be used for the classification as they are more reliable than classification based on composition of the product.

Type of test, species, model system (Guideline)	Result	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral, rat	> 2000 mg/kg bw	None	Based on results of studies on the representative formulation (Callisto 100 SC)
LD <sub>50</sub> dermal, rat	> 2000 mg/kg bw	None	Based on results of studies on the representative formulation (Callisto 100 SC)
LC <sub>50</sub> inhalation, <del>rat</del>	> 5 mg/L	None	Calculation method (additivity formula)
Skin irritation, rabbit	none	none	Based on results of studies on the representative formulation (Callisto 100 SC)
Eye irritation, rabbit	Irritant	Eye Irrit.2, H319	Based on results of studies on the representative formulation (Callisto 100 SC)

Skin sensitisation, guinea pig	non-sensitizing	None	Based on results of studies on the representative formulation (Callisto 100 SC)
Supplementary studies for combinations of plant protection products	-	-	-

### 3.5.2 Operator exposure

The operator exposure was assessed against the AOEL for mesotrione (EFSA Journal 2016;14(3):4419). The dermal absorption study for the reference product Callisto 100 SC with the same recipe as MEZ-HER 100 SC were used for the calculations.

The use of MEZ-HER 100 SC containing mesotrione (100 g/kg) causes acceptable health risk for unprotected operator. However, taking into account the classification of the product (Eye Irrit. 2, H319, Repr. Cat. 2, H361d) eye/face shield during M&L and protective gloves are mandatory.

Thus, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:

*„Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezon) w trakcie przygotowywania cieczy roboczej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu”*

“Wear protective gloves, eye/face protection and work wear (coverall) during mixing/loading and protective gloves and work wear during application”.

### 3.5.3 Worker exposure

The worker exposure was assessed against the AOEL for mesotrione (EFSA Journal 2016;14(3):4419). The dermal absorption study for the reference product Callisto 100 SC with the same recipe as MEZ-HER 100 SC were used for the calculations.

The use of MEZ-HER 100 SC containing mesotrione (100 g/kg) causes acceptable health risk for a worker wearing work wear during 2 hour working day (inspection).

However, bearing in minds the hygienic rules, the use of protective gloves is recommended when entering treated area.

Following sentence is recommended by the evaluator to be placed in the section of precautions for the workers:

*„Stosować rękawice ochronne oraz odzież roboczą podczas wchodzenia na teren poddany opryskowi .”*

“Wear protective gloves and work wear when entering treated area.”

### 3.5.4 Bystander and resident exposure

The bystander/resident exposure was assessed against the AOEL for mesotrione (EFSA Journal 2016;14(3):4419). The dermal absorption study for the reference product Callisto 100 SC with the same recipe as MEZ-HER 100 SC were used for the calculations.

The use of MEZ-HER 100 SC according to the list of intended uses and anticipating the introduction of buffer zone presented in GAP Table, cause acceptable health risk for bystander/resident (adult and child)

according to AOEM.

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

#### **3.6.1 Residues**

##### **Storage stability**

The stability of residues during storage of samples was reviewed during the Annex I inclusion process and no further data is required.

Mesotrione is considered to be stable under freezer storage at  $-18^{\circ}\text{C}\pm 5^{\circ}\text{C}$  for at least 42 months in maize grain and 31 months in maize forage. Frozen storage stability at  $-18^{\circ}\text{C}\pm 5^{\circ}\text{C}$  of MNBA in maize grain and forage was demonstrated for at least 42 months.

##### **Metabolism in plants and animals**

Metabolism in plants and livestock data was provided during the EU review of mesotrione.

Plant residue definition for monitoring Mesotrione (cereals and pulses/oilseeds only) - EFSA journal 2016;14(3):4419,

Reg. (EU) 2017/626 and Reg. (EU) 2024/1077: Mesotrione.

Plant residue definition for risk assessment:

Food commodities: Mesotrione (cereals and pulses/oilseeds only)

Feed commodities: Mesotrione and AMBA (including its conjugates) (Cereals, pulses and oilseeds only – Conventional crops) – Provisional. - EFSA journal 2016;14(3):4419

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

Proposed GAP for maize (1 application, BBCH 14-15, 100 g as/ha) is less critical than EU GAP (SAN-TE/11654/2016, 23 March 2017).

Sufficient unprotected data were submitted and evaluated in DAR and RAR, and considered enough to support the intended use in maize in NEU. Unprotected data are accepted in RAR.

An exceedance of the current MRL of 0.01 mg/kg for mesotrione on maize as laid down in Reg. (EC) No 396/2005 is not expected.

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

No new data were submitted in the framework of this application and no required.

Animals are not exposed to residues via feed above the trigger value (0.004 mg/kg). Therefore livestock feeding studies are not required.

Dietary burden calculation with regard to AMBA conjugates residues in maize forage, fodder and total residues in maize grain from the metabolism data were tentatively estimated by EFSA (*EFSA Journal* 2016;14(3):4419).

EFSA (2016): *This assessment has to be reconsidered pending the outcome of data gap set for clarification of the genotoxic potential of AMBA and of its toxicological profile.*

According to the *EFSA Supporting publication* 2018:EN-1527, genotoxic potential of AMBA is considered clarified:

*EFSA: we agree with the RMS conclusion that the micronucleus test gave sufficient evidence of lack of genotoxic (clastogenic and aneugenic) potential of the metabolite AMBA since bone marrow exposure was demonstrated after 2 dosing with the substance with 24 h interval and measurement of AMBA in*



*whole blood. We agree with the RMS that the confirmatory data requirement (1) has been fulfilled. It is however noted that the data gap identified in the EFSA conclusion (EFSA, 2016) regarding the relative toxicity of the metabolite compared with mesotrione has not been addressed.*

Since the residues are below 0.01 mg/kg, no further calculations are required.

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

As residues of Mesotrione are not expected in treated crops, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

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

No new data were submitted in the framework of this application and no required.

Field rotational crop study are not triggered considering the very low TRRs in rotational crops after a bare soil application at ca. 1N rate. No mitigation measures for rotational crops are necessary.

#### **Other / special studies**

Studies are not required. Maize is not a melliferous crop foraged by bees.

### **3.6.2 Consumer exposure**

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1)

<b>ADI</b>	0.01 mg/kg bw / day
<b>TMDI (% ADI) according to EFSA PRIMo rev. 3.1</b>	12 % (based on NL toddler Diet) Highest contributors: 6% Milk: cattle 1% Apples 0.7% Maize/corn
<b>IEDI (% ADI) according to EFSA PRIMo rev. 3.1</b>	not relevant, TMDI < 100%
<b>ARfD</b>	0.02 mg/kg bw/day
<b>IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*</b>	<u>Unprocessed commodities - children</u> maize: 0.3% (UK infants) <u>Unprocessed commodities - adults:</u> maize: 0.1% (FI men) <u>Processed commodities - children</u> maize/oil: 1% (NL toddler) maize / processed (not specified): 0.1% (NL toddler) <u>Processed commodities - adults</u> maize/oil: 0.6% (NL general population)
<b>NTMDI (% ADI) **</b>	not relevant
<b>NEDI (% ADI)**</b>	not relevant
<b>NESTI (% ARfD) **</b>	not relevant

\* include raw and processed commodities if both values are required for PRIMo

\*\* if national model is available

The proposed uses of mesotrione in the formulation MEZ-HER 100 SC does not represent unacceptable acute and chronic risks for the consumer.

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

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

- For the purpose of evaluation of MEZ-HER 100 SC please refer to B8 mesotrione MEZ-HER 100 SC and Renewal RR for Callisto 100 SC.

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

For the purpose of this application additional PEC<sub>gw</sub> modelling was performed. In respect to the harmonization guidance for Poland, posted on the website of the Ministry of Agriculture and Rural Development, calculations for Predicted Environmental Concentrations in groundwater (PEC<sub>gw</sub>) with the latest versions of the FOCUS-PELMO v6.6.4, FOCUS - PEARL v5.5.5 and MACRO v5.5.4. Modeling using the EU agreed input parameters, application dates as suggested by App Date 3.06 and relevant crop interception according FOCUS groundwater guidance (2014) was conducted.

The 80th percentiles of the predicted annual average leachate concentrations of mesotrione and its metabolites were below 0,1 µg/L in all calculated scenarios.

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

the purpose of evaluation of MEZ-HER 100 SC please refer to refer to B8 mesotrione MEZ-HER 100 SC and Renewal RR for Callisto 100 SC.

#### **3.7.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)**

For the purpose of evaluation of MEZ-HER 100 SC please refer to refer to B8 mesotrione MEZ-HER 100 SC Renewal RR for Callisto 100 SC.

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

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

##### **Birds**

No data is provided in support of the application for authorization of **Mecorn 100 SC**.

The risk assessment for birds performed for Callisto 100 SC are suitable for the use of Mecorn 100 SC proposed in GAP.

**On the basis of performed calculations for Callisto 100 SC, acceptable acute and long-term risk to birds may be concluded from proposed uses of Mecorn 100 SC.**

The risk assessment for exposure via drinking water from puddles also showed acceptable risk.

##### **Mammals**

No data is provided in support of the application for authorization of **Mecorn 100 SC**.

The risk assessment for mammals performed for Callisto 100 SC are suitable for the use of Mecorn 100 SC proposed in GAP.

**On the basis of performed calculations for Callisto 100 SC, acceptable acute and long-term risk to mammals may be concluded from proposed uses of Mecorn 100 SC (100 g s.a./ha).**

The risk assessment for exposure via drinking water from puddles also showed acceptable risk.

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

#### **Aquatic organisms**

No data is provided in support of the application for authorization of **Mecorn 100 SC**.

The risk assessment for aquatic organisms performed for Callisto 100 SC are suitable for the use of Mecorn 100 SC proposed in GAP.

**On the basis of performed calculations for Callisto 100 SC, acceptable risk to aquatic organisms may be concluded from proposed uses of Mecorn 100 SC.**

The PEC<sub>sw/sed</sub> performed for Callisto 100 SC are suitable for the use of Mecorn 100 SC proposed in GAP.

The input parameters considered by the Applicant for surface water modelling were agreed by the zRMS.

In order to mitigate the risk, Step 4 simulations were performed with assumption of 5, 10 and 20 m spray drift buffer and 10 m and 20 m vegetative filter strips (for run-off scenarios) or 50% nozzle reduction. The run-off reduction was assumed in line with FOCUS Landscape and Mitigation recommendations (FOCUS, 2007).

Based on the risk assessment for **Callisto 100 SC**, a safe use for intended uses for **Mecorn 100 SC** could be identified, provided that appropriate risk mitigation measures are taken into account. The risk mitigation measures should be considered at MSs level. No additional risk assessment is required.

#### **PL**

Acceptable risk with no need for mitigation measures was demonstrated in scenarios representative for Poland (D3, D4 and R1) for application rate of 1.0 L/ha (corresponding to 100 g a.s./ha).

### **3.8.3 Effects on bees**

The risk assessment for bees evaluated in **Callisto 100 SC** cover use of **Mecorn 100 SC**.

The acute toxicity data for mesotrione and Callisto (A12739A) are in line with EU agreed endpoints reported in EFSA Journal 2016;14(3):4419. The chronic toxicity of Callisto to adult bees as well as toxicity of the formulation to larvae are also in agreement with EU agreed values. All the calculated hazard quotients are less than the relevant trigger of 50, indicating that the acute oral and contact risk to bees is acceptable following use of Callisto according to the proposed use pattern.

In addition to that, the Applicant submitted studies on chronic toxicity of mesotrione to adult bees and larvae (Wendling, 2018 and Eckert, 2016). It is, however, noted that data regarding chronic toxicity to adult bees and larvae obtained in studies performed with the representative formulation (Callisto) were deemed sufficient at the EU level and no data gap in this area was identified in EFSA Journal 2016;14(3):4419. Taking this into account it may be concluded that data requirements as set by the Commission Regulation (EU) No 284/2013 are fulfilled and no additional studies are deemed necessary. Additional studies performed with the active substance were thus not evaluated by the zRMS as sufficient data package is already available from the EU review. Concerned Member States that require risk assessment performed in line with EFSA bee guidance (2013) may utilize the EU toxicity data available

for the formulated product. **The risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level. Final decision should be taken into account at MSs level.**

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

#### Non-target arthropods other than bees

No data is provided in support of the application for authorization of **Mecorn 100 SC**. The intended uses in GAP for the formulation Product **Callisto 100 SC** are within those considered acceptable for registration of **Mecorn 100 SC**. No unacceptable effects are anticipated on communities of terrestrial non-target arthropods due to the use of **Mecorn 100 SC** according proposed use in GAP.

### 3.8.5 Effects on soil organisms

#### Effect on non-target soil meso- and macrofauna

No data is provided in support of the application for authorization of **Mecorn 100 SC**. The intended uses product **Callisto 100 SC** are within those considered acceptable for registration of **Mecorn 100 SC**. The long-term risk assessment presented for earthworms and other soil non-target macro-organisms based on the endpoints from the studies performed on formulation of **Callisto 100 SC**. The risk assessment is appropriate to be used for **Mecorn 100 SC**. Use of **Mecorn 100 SC** is not expected to pose risk to soil macro-organisms. No additional risk assessment is not required.

#### Effects on soil microbial activity

No data is provided in support of the application for authorization of **Mecorn 100 SC**. The intended uses product **Callisto 100 SC** are within those considered acceptable for registration of **Mecorn 100 SC**. The risk assessment presented for micro-organisms on the endpoints from the studies performed on formulation of **Callisto 100 SC** has been accepted for **Mecorn 100 SC**. The risk assessment is appropriate to be used for **Mecorn 100 SC**. According to the Registration Report for **Callisto 100 SC** the risk assessment for microorganisms have been accepted. On the basis of performed calculations in **Callisto 100 SC** report, acceptable risk assessment to microorganisms may be concluded from proposed uses of **Mecorn 100 SC**. The risk to soil micro-organisms from uses of **Mecorn 100 SC** is expected to be low. No additional risk assessment is not required.

### 3.8.6 Effects on non-target terrestrial plants

#### Non-target plants:

No data is provided in support of the application for authorization of **Mecorn 100 SC**. The intended uses product **Callisto 100 SC** are within those considered acceptable for registration of **Mecorn 100 SC**. The risk assessment presented for non-target plants on the endpoints from the studies performed on formulation of **Callisto 100 SC** has been accepted for **Mecorn 100 SC**. The risk assessment is appropriate to be used for **Mecorn 100 SC**. According to the Registration Report for **Callisto 100 SC** the risk assessment for non-target plants have been accepted. On the basis of performed calculations in **Callisto 100 SC** report, acceptable risk assessment to non-target plants may be concluded from proposed uses of **Mecorn 100 SC**.

PL:

On the basis of performed calculations following risk mitigation measures are required to protect non-target terrestrial plants:

- 20 m unsprayed buffer zone to non-agricultural land, or
- 10 m unsprayed buffer zone to non-agricultural land combined with reduction of the spray drift by 50%, or
- reduction of the spray drift by 75%.

Concerned Member States must decide on applicability of the indicated mitigation measures at the product authorisation in their countries.

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

Not relevant for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. For the purpose of evaluation of MEZ-HER 100 SC please refer to Renewal RR for Callisto 100 SC.

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

Not relevant for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. For the purpose of evaluation of MEZ-HER 100 SC please refer to Renewal RR for Callisto 100 SC.

## **4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)**

MEZ-HER 100 SC contains mesotrione which is non approved as a candidate for substitution. As a conclusion providing of the comparative assessment plant protection product MEZ-HER 100 SC is not required.

## **5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization**

No data gaps.
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## **Appendix 1    Copy of the product authorization**

## Appendix 2 Copy of the product label

**Fizyko-chemia:** Okres ważności 3 lata w opakowaniach wykonanych z HDPE, HDPE/PA (COEX), fHDPE na podstawie 3-letnich badań stabilności w temperaturze otoczenia przeprowadzonych dla środka referencyjnego w opakowaniach z HDPE.

**Los i zachowanie w środowisku:** brak uwag

**Skuteczność:** Wprowadzono zmiany do listy zaakceptowanych gatunków chwastów i ich wrażliwości na Mecorn 100 SC. Dodano informację iż zaleca się stosowanie produktu na kukurydzy uprawianej na ziarno, kiszonkę i bioetanol. Pozostałych zapisów etykiety – nie zmieniano.

**Sekcja pozostałości:** brak uwag.

**Ekotoksykologia:**

1. Dopisano zwrot P501.
2. Usunięto zapisy dotyczące stref ochronnych dla organizmów wodnych (dla dawki 1,0 L/ha nie ma konieczności wprowadzania narzędzi zarządzania ryzykiem w celu ochrony organizmów wodnych).
3. Poprawiono zapisy dotyczące narzędzi zarządzania ryzykiem niezbędnych w celu ochrony roślin lądowych niebędących celem zwalczania.

~~Label was separately submitted.~~

**Posiadacz zezwolenia:**

Pestila Spółka z ograniczoną odpowiedzialnością, Studzianki 24a, 97-320 Wolbórz,  
tel./fax: +48 446164375, e-mail: info@pestila.pl.

### – MECORN 100 SC

– Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej: **mezotrion** (substancja z grupy trójketonów)  
- **100 g/l** (9,1%)

Substancje czynne niebędące substancją czynną, stwarzające zagrożenie:  
oktan-1-ol, etoksylogowany eter izodecylowy, kwas ortofosforowy.

Zezwolenie MRiRW nr R - /2023 z dnia .2023 r.



**Uwaga**

H315

Działa drażniąco na skórę.

H318	–	Powoduje poważne uszkodzenie oczu.
H319	–	Działa drażniąco na oczy.
H361d	–	Podejrzewa się, że działa szkodliwie na dziecko w łonie matki.
H410	–	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH 401	–	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P202	–	Nie używać przed zapoznaniem się i zrozumieniem wszystkich środków bezpieczeństwa.
P280	–	Stosować rękawice ochronne/odzież ochronną/ oraz ochronę oczu/ochronę twarzy.
P305+P351+P338	–	W PRZYPADKU DOSTANIA SIĘ DO OCZU: ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P308 + P313	–	W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P302 + P352	–	W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody z mydłem.
P337 + P313	–	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady /zgłosić się pod opiekę lekarza.
P391	–	Zebrać wyciek.
P501	–	Zawartość/pojemnik usuwać do recyklingu bądź składowania na składowiskach odpowiednich dla pestycydów lub spalania w odpowiednich instalacjach

## OPIS DZIAŁANIA

Herbicyd w formie stężonej koncentratu stężonej zawiesiny do rozcieńczania wodą (SC), o działaniu układowym, stosowany nalistnie, przeznaczony do wiosennego zwalczania chwastów jedno i dwuliściennych w kukurydzy.

Zgodnie z klasyfikacją HRAC substancja czynna mezotrion zaliczana jest do grupy 27 (dawniej F2).

Środek przeznaczony do stosowania przy użyciu opryskiwaczy polowych.

## DZIAŁANIE NA CHWASTY

MECORN 100 SC jest herbicydem zawierającym mezotrion. Substancja ta zaliczana jest do inhibitorów biosyntezy karotenoidów, następnie powodując zniszczenie chlorofilu, objawiające się bieleniem liści.

Preparat pobierany jest głównie poprzez liście oraz dodatkowo poprzez korzenie chwastów i następnie szybko przemieszczany w roślinie, hamując ich wzrost i rozwój. Pierwsze objawy działania środka można zaobserwować po 5-7 dniach od wykonania zabiegu. Zamieranie chwastów następuje po około 14 dniach od zabiegu.

Środek stosować po wschodach chwastów w okresie, gdy mają one rozwinięte 2-6 liści, a najskuteczniejsze działanie wykazuje na chwastach będących w fazie 4-tego liścia.

**Chwasty wrażliwe:** szarłat szorstki (AMARE), rumian polny (ANTAR), tasznik pospolity (CAPBP), kromska biała (CHEAL), chwastnica jednostronna (ECHCG), przytulia czepna (GALAP), żółtlica drobnokwiatowa (GASPA), jasnota purpurowa (LAMPU), rdestówka powo-



~~iewata (POLCO)~~, gwiazdnica pospolita (STEME), tobołki polne (THLAR), fiołek polny (VIO-AR),

**Chwasty średnio wrażliwe:** ~~dymnica pospolita (FUMOF)~~, komosa biała (CHEAL), chwastnica jednostronna (ECHCG), samosiewy rzepaku (BRSNN)

## STOSOWANIE ŚRODKA

**Kukurydza uprawiana na ziarno, kiszonkę i bioetanol**

**Maksymalna dawka dla jednorazowego zastosowania:** 1 L/ha

**Zalecana dawka dla jednorazowego zastosowania:** 1 L/ha

Termin stosowania środka: stosować wiosną w fazie 4-5 liści kukurydzy (BBCH 14-15)

Zalecana ilość wody: **200-300 l/ha**

Zalecane opryskiwanie: średniokropliste

**Maksymalna liczba zabiegów w sezonie wegetacyjnym:** 1

## NASTĘPSTWO ROŚLIN

W przypadku konieczności wcześniejszej likwidacji plantacji potraktowanej środkiem (w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na polu można uprawiać kukurydzę lub życie trwałą. Po wykonaniu głębokiej orki oprócz w/w roślin można także uprawiać sorgo.

Po zbiorze kukurydzy uprawianej w normalnych warunkach wegetacji, odchwaszczonej środkiem MECORN 100 SC maksymalnie do 1 lipca oraz po wykonaniu głębokiej orki można wysiewać wszystkie rośliny uprawne. W przypadku uprawy roślin wrażliwych tj. buraka, roślin strączkowych, rzepaku ozimego, słonecznika zwyczajnego i warzyw oraz wcześnie sianych zbóż ozimych możliwe jest wystąpienie uszkodzeń.

W skrajnie niekorzystnych warunkach (gleby piaszczyste, gleby łatwo przesychające, gleby o niskim pH (< 6,0), gleby o wysokiej zawartości substancji organicznej (>4,0%), niskiej aktywności biologicznej, wyjątkowo niskich temperaturach w okresie zimowym, wyjątkowo niskiej wilgotności gleby latem i/lub jesienią i/lub zimą, nakładania się powierzchni opryskanej preparatem, nadmiernie ugniecionej gleby) mogą wystąpić tymczasowe wybielenia, zahamowanie wzrostu, zmniejszenie obsady w roślinach wrażliwych (buraki, rośliny strączkowe, słonecznik zwyczajnego i warzywa). Dlatego też uprawa w/w roślin jako roślin następczych nie jest zalecana, gdy pH gleby jest znacznie poniżej 6,0, lub jeśli po zastosowaniu środka w poprzednim sezonie wystąpił długotrwały okres posuchy. Głęboka orka po uprawie kukurydzy i pH gleby ponad 6,0 znacząco zmniejszają ryzyko uszkodzeń tych roślin.

## ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

**Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):**

nie wymagany.

1. Ze względu na możliwość wystąpienia objawów fitotoksyczności w liniach wsobnych kukurydzy, na plantacjach nasiennych kukurydzy oraz plantacjach kukurydzy cukrowej, przed zastosowaniem środka **zaleca się** wykonanie na każdej uprawie próbnego zabiegu w celu sprawdzenia czy nie występują objawy uszkodzenia roślin lub skontaktować się z doradcą albo przedstawicielem podmiotu posiadającego zezwolenie.

**2. Strategia zarządzania odpornością**

W celu zminimalizowania ryzyka wystąpienia i rozwoju zjawiska odporności chwastów na herbicydy należy, zgodnie z Dobrą Praktyką Rolniczą:

- postępować zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, oraz w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
- dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
- stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować mieszaniny herbicydów (substancji czynnych) o różnym mechanizmie działania,
- stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
- używać kwalifikowanego materiału siewnego,
- czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
- informować posiadacza zezwolenia o nie satysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

### 3. Środka nie stosować:

- na rośliny osłabione lub uszkodzone przez szkodniki, przymrozki, zalanie lub suszę,
- podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.

### 4. Podczas stosowania środka nie dopuścić do:

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

## **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Wstrząsnąć zawartością opakowania przed użyciem. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości.

Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać. W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy należy dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

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

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

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

Po pracy aparaturę dokładnie umyć oraz trzykrotnie przepłukać wodą.

## **WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA**

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

#### **Środki ostrożności dla osób stosujących środek:**

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

Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież roboczą (kombinezom) w trakcie przygotowywania cieczy roboczej oraz rękawice ochronne i odzież roboczą w czasie wykonywania zabiegu.

~~Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

#### **Środki ostrożności związane z ochroną środowiska naturalnego:**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać uwalniania do środowiska, niezgodnego z przeznaczeniem

~~W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.~~

~~W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie od terenów nieużytkowanych rolniczo, strefy ochronnej o szerokości:~~

- ~~– 20m, lub~~
- ~~– 10m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy roboczej podczas zabiegu o 50%, lub~~
- ~~– 1m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy roboczej podczas zabiegu o 75%.~~

W celu ochrony roślin niebędących celem działania środka konieczne jest:

- wyznaczenie strefy ochronnej o szerokości 20 m od terenów nieużytkowanych rolniczo, lub
- wyznaczenie strefy ochronnej o szerokości 10 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej o 50%, lub
- zastosowanie rozpylaczy redukujących znoszenie cieczy użytkowej o 75%.

**Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):**

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

**Okres od ostatniego zastosowania środka na rośliny do dnia w którym można siać lub sadzić rośliny uprawiane następnie:**

Należy uwzględnić następstwo roślin

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

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

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

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

### **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

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

~~W przypadku złego samopoczucia skontaktować się z lekarzem lub/i Ośrodkiem Zatrucia.~~

W przypadku dostania się do oczu: ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

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

W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 3 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

### **Appendix 3 Letter of Access**

Letter of Access is provided in a separate appendix.

## Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

### 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
<b>Section B1-B2 and B4: Identity, Physical and Chemical Properties, Further information</b>							
KCP 2.1 KCP 2.2.2 KCP 2.3.1 KCP 2.3.3 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Digrandi S.	2023	Determination of the Physical-Chemical properties of MEZ-HER 100 SC. Product Before and after Accelerated Storage for 14 days at 54±2 °C and low temperature storage for 7 days at 0±2°C. Report No 23214-02C Renolab S.r.l. GLP Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*
KCP 2.2.1	Mazzei A.	2023	Determination of Explosive Properties on the Sample MEZ-2304703 Innovhub – Stazioni Sperimentali per l'Industria S.r.l. GLP	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GLP.	Pestila*

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Published: No				
<b>Section B3: Efficacy Data and Information</b>							
KCP 3.2/01	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_340 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/02	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_341 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/03	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_343 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/04	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_344 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/05	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_345 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.2/06	Szemendera A.	2022	Efficacy of MEZ-HER 100 SC in post-emergence weed control in maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 181_01_F22_346	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP: Yes Published: No				
KCP 3.4/01	Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in silage maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_347 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/02	Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in grain maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_348 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/03	Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in silage maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_349 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/04	Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in grain maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_350 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
KCP 3.4/05	Szemendera A.	2022	Selectivity of MEZ-HER 100 SC applied in weed control in silage maize, Poland 2022 Fertico Sp. z o.o., Poland; Report No.: 182_01_F22_351 GEP: Yes Published: No	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance with GEP.	Pestila*
<b>Section B5: Analytical Methods</b>							
KCP 5.1.1	Digrandi S.	2023	Analytical Method Validation for Active Ingredient and impurities Content Determination of the MEZ-HER 100 SC	N	Y	New data for formulation, not previously submitted or evaluated. Study conducted in compliance	Pestila*



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report No 23214-01C Renolab S.r.l. GLP: Yes Published: No			with GLP.	
<b>Section B6: Mammalian toxicology</b>							
KCP 7.1.1 / 01		2005	Mesotrione 100 G/L SC Formulation (A12739A): Acute Oral Toxicity Study in the Rat (Up and Down Procedure) GLP not published	Y	YN	Data protection started with: R-25/2009	SYN
KCP 7.1.2 / 01		2005a	Mesotrione 100g/l SC Formulation (A12739A): Acute Dermal Toxicity Study In Rats GLP not published	Y	YN	Data protection started with: R-25/2009	SYN
KCP 7.1.4 / 01		2005b	MESOTRIONE 100 G/L SC FORMULATION (A12739A): Primary Skin Irritation Study in Rabbits (4-Hour Semi-occlusive Application) GLP not published	Y	YN	Data protection started with: R-25/2009	SYN
KCP 7.1.5 / 01		2005c	Mesotrione 100g/l SC Formulation(A12739A): Primary Eye Irritation Study in Rabbits GLP not published	Y	YN	Data protection started with: R-25/2009	SYN
KCP 7.1.6 / 01		2005	Dermal Sensitization Study in Guinea Pigs (Buehler Method) with Mesotrione SC (100) (A12739A) GLP not published	Y	YN	Data protection started with: R-25/2009	SYN

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.3 / 01		2013	Mesotrione 100 SC (A12739A) - In Vitro Absorption through Human Dermatomed Skin using [14C-Radiolabelled]-Mesotrione GLP not published	N	YN	Data protection started with: R 25/2009	SYN

#### Section B8: Environmental Fate

KCP 9.2/01	Hara-Skrzypiec A.	2023	MEZ-HER 100 SC- calculation of Predicted Environmental Concentrations of mesotrione and its metabolites in ground water using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models. Company Report No: EST/18/2023 Source: ESTICON Sp. z o.o., Poland GEP: No Published: No	N	N	Not relevant	Pestila*
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\*Pestila Spółka z ograniczoną odpowiedzialnością (short name: Pestila Sp. z o.o.)

#### 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Section B5: Analytical Methods							
KCA 4.2 / 01	Watson G.	2013a	Mesotrione - Validation of the QuEChERS Method for the	N	N	-	SYN

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Determination of Residues of mesotrione in Crop Matrices by LC-MS/MS Syngenta Eurofins Agrosience Services Ltd, Wilson, UK, S12-03251 GLP, not published Syngenta File No ZA1296_10090				
KCA 4.2 / 02	Tessier V.	2013	Mesotrione - Independent Laboratory Validation of the QuEChERS Method for the Determination of Residues of Mesotrione in Crop Matrices by LC-MS/MS Syngenta Eurofins Agrosience Services Chem SAS, Vergèze, France, S12-04607 GLP, not published Syngenta File No ZA1296_10129	N	N	-	SYN
KCA 4.2 / 04	Jutsum L.	2013	Mesotrione – Validation of Draft Residue Method GRM007.10A for the Determination of Mesotrione and its Metabolites AMBA and MNBA in Soil Syngenta CEMAS, North Ascot, United Kingdom, CEMR-5657-REG GLP, not published Syngenta File No ZA1296_10088	N	N	-	SYN
KCA 4.2 / 06	Jutsum L.	2013a	Mesotrione - Validation of Draft Residue Method GRM007.09A for the Determination of Mesotrione and its metabolites AMBA and MNBA in Water Syngenta CEMAS, North Ascot, United Kingdom, CEMR-5658-REG GLP, not published Syngenta File No ZA1296_10087	N	N	-	SYN
KCA 4.2 / 07	Wiesner F., Breyer N.	2013	Mesotrione - Independent Laboratory Validation of Analytical Method GRM007.09A for the Determination of Residues of Mesotrione and its Metabolites in AMBA and MNBA Water Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S13-04185 GLP, not published Syngenta File No ZA1296_10174	N	N	-	SYN
KCA 4.2 / 09	Jutsum L.	2013c	Mesotrione - Validation of Residue Method GRM007.08A for the Determination of Mesotrione in Air	N	N	-	SYN

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Syngenta CEMAS, North Ascot, United Kingdom, CEMR-5403-REG GLP, not published Syngenta File No ZA1296_10084				
KCA 4.2	Watson G.	2013	Mesotrione - Validation of the QuEChERS Method for the Determination of Residues of mesotrione in Animal Matrices by LC-MS/MS Syngenta Eurofins Agroscience Services Ltd, Wilson, UK, S12-03250 GLP not published Syngenta File No ZA1296_10093	N	N	-	SYN
KCA 4.2	Bernal J.	2013	Mesotrione - Independent Laboratory Validation of the QuEChERS Method for the Determination of Residues of Mesotrione in Animal matrices by LC-MS/MS Syngenta Eurofins Agroscience Services Chem SAS, Vergèze, France, S12-04608 GLP not published Syngenta File No ZA1296_10130	N	N	-	SYN
KCA 4.2 / 09	Jutsum L.	2013c	Mesotrione - Validation of Residue Method GRM007.08A for the Determination of Mesotrione in Air Syngenta CEMAS, North Ascot, United Kingdom, CEMR-5403-REG GLP, not published Syngenta File No ZA1296_10084	N	N	-	SYN
<b>Section B7: Metabolism and Residues</b>							
KCA 6.1 / 01	Wiebe LA, Peyton CS	1999	ZA1296: Stability of ZA1296 & the Metabolite MNBA in Frozen Crops Zeneca Agrochemicals, Jealott's Hill, United Kingdom, RR 97-042B FIN GLP, not published Syngenta File No ZA1296/0125	N	N	-	SYN
KCA 6.2.1 / 01	Brumback D.	2003	[Cyclohexane-2-14C] Mesotrione: Nature of the Residue in Peanuts Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001287-01	N	N	-	SYN

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			1287-01 GLP, not published Syngenta File No ZA1296/1350				
KCA 6.2.1 / 02	Brown K.	2003	[Phenyl-U-14C] Mesotrione: Nature of the Residue in Peanuts Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001286-01 1286-01 GLP, not published Syngenta File No ZA1296/1349	N	N	-	SYN
KCA 6.2.1 / 03	Dohn D., Chu J.	2012	14C-Mesotrione - Nature of the Residue in Herbicide Tolerant (HT) Soybeans Syngenta PTRL West, Hercules CA, USA, Syngenta Crop Protection, LLC, Greensboro, NC, USA, Landis International, Valdosta, USA, Agvise Laboratories, Northwood, ND, USA, 1943W, 860.1300-09-433-07B-03 GLP, not published Syngenta File No ZA1296_50531	N	N	-	SYN
KCA 6.3.1 / 07	Klimmek S., Gizler A.	2008	MESOTRIONE AND NICOSULFURON: RESIDUE STUDY ON MAIZE IN NORTHERN FRANCE IN 2007 Syngenta - Jealott's Hill, Bracknell, United Kingdom Eurofins - Dr Specht & Partner, Hamburg, Germany, T011368-07 GLP, not published Syngenta File No A14351BX_10205	N	N	-	SYN
KCA 6.3.1 / 09	Schulz H	2010	Mesotrione and Nicosulfuron - Residue Study on Maize in France (North) in 2008 Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T009530-07-REG GLP, not published Syngenta File No ZA1296_10049	N	N	-	SYN
KCA1 6.3.1 / 01	Barnes J.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1995 (WRC-96-114) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 96-078B GLP not published Syngenta File No ZA1296/0409	N	N	-	SYN

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA1 6.3.1 / 02	Heillaut C	2009	Glyphosate (ASF71), Mesotrione (ZA1296) and S-Metolachlor (CGA77102) - Residue Study on GA21 (MON----21-9) Corn in France (North) and Czech Republic in 2007 Syngenta ADME - Bioanalyses, Vergeze, France, T011085-06 GLP not published Syngenta File No A15189G_10009	N	N	-	SYN
KCA1 6.3.1 / 03	Heillaut C	2009a	Glyphosate, Mesotrione and S-Metolachlor - Residue Study on GA21 (MON-00021-9) Corn in Denmark and Sweden in 2008 Syngenta ADME - Bioanalyses, Vergeze, France, T009533-07-REG GLP not published Syngenta File No A15189G_10014	N	N	-	SYN
KCA1 6.3.1 / 04	Meyer M	2011	Mesotrione - Residue Study on Field Corn in Germany and the United Kingdom in 2009 Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T000920-09-REG GLP not published Syngenta File No A14203B_10105	N	N	-	SYN
KCA1 6.3.1 / 05	Klimmek S., Gizler A.	2008	MESOTRIONE AND NICOSULFURON: RESIDUE STUDY ON MAIZE IN NORTHERN FRANCE IN 2007 Syngenta - Jealott's Hill, Bracknell, United Kingdom Eurofins - Dr Specht & Partner, Hamburg, Germany, T011368-07 GLP not published Syngenta File No A14351BX_10205	N	N	-	SYN
KCA1 6.3.1 / 06	Schulz H	2010	Mesotrione and Nicosulfuron - Residue Study on Maize in France (North) in 2008 Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T009530-07-REG GLP not published Syngenta File No ZA1296_10049	N	N	-	SYN

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.1.2.2 / 07	Funkenhaus A, Giessing B	2010	Exposure of mammals in maize fields in France - Attractiveness of maize fields and relevant species Syngenta - Jealott's Hill, Bracknell, United Kingdom Rifcon, Heidelberg, Germany, R09012-2 GLP not published Syngenta File No NA_11991	N	YN	Data protection started with: R-25/2009	SYN
KCP 10.1.2.2 / 08	Wolf C.	2005	Generic field monitoring of birds and mammals on maize and beet fields in Austria Bayer Crop Science AG, Monheim, Germany Bayer Crop Science AG, Monheim, Germany, WFC/FS017 GLP not published Syngenta File No N/1155	N	Y	Syngenta understands that the data owner benefits from data protection and should be contacted for further details	BCS (SYN access)
KCP 10.1.2.2 / 09	Grimm T, Dietzen D, Von Blanckenhagen F.	2014	Generic field study on small mammals - focal species and wood mouse (Apodemus sylvaticus) PT in maize fields in Germany Oxon Italia S.p.A., Pero, Italy RIFCON GmbH, Hirschberg, Germany, R12225 GLP not published Syngenta File No NA_13410	N	Y	Syngenta understands that the data owner benefits from data protection and should be contacted for further details	OXN (SYN access)
KCP 10.2 / 01		2005	Mesotrione 100 g/L SC formulation (A12739A): Acute toxicity to carp (Cyprinus carpio) GLP not published	Y	Y	Data protection started with: R-25/2009	SYN
KCP 10.2 / 02	Ricketts D., Langridge G.	2005	Mesotrione 100 g/L SC (A12739A): Acute toxicity to the Cladoceran Daphnia magna under static conditions Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RJ3714B GLP not published Syngenta File No ZA1296/2042	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.2 / 03	Volz E.	2005	Mesotrione 100 SC Formulation (A12739A): Toxicity to Pseudokirchneriella subcapitata (formerly Selenastrum	N	Y	Data protection started with: R-25/2009	SYN

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			capricornutum) in a 96-hour algal growth inhibition test Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, A18325 GLP not published Syngenta File No ZA1296/2049				
KCP 10.2 / 04	Zawadsky C.	2013	Mesotrione SC (A12739A) - Assessment of Toxic Effects on the duckweed Lemna gibba in a 7 day Semi-Static Test and 14 day Recovery Period Syngenta Crop Protection AG, Basel, Switzerland Eurofins Agrosience Services EcoChem GmbH, N-Osch., Germany, S12-03986 GLP not published Syngenta File No A12739A_10273	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.3.1 / 01	Kleebaum K.	2013	Mesotrione SC (A12739A) - Semi-chronic toxicity to the honeybee larvae Apis mellifera L. under laboratory conditions (in vitro) Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 073 B GLP not published Syngenta File No A12739A_10464	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.3.1 / 02	Kleebaum K.	2013a	Mesotrione SC (A12739A) - Chronic toxicity to the honeybee Apis mellifera L. in a 10 day continuous laboratory feeding study Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 074 B GLP not published Syngenta File No A12739A_10465	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.3.1 / 03	Franke M.	2013	Mesotrione SC (A12739A) - Acute toxicity to the honeybee Apis mellifera L. under laboratory conditions Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 001 B GLP not published Syngenta File No A12739A_10015	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.3.2 /	Fallowfield L.	2012	Mesotrione SC (A12739A) - A rate-response laboratory bioassay	N	Y	Data protection started with:	SYN



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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
01			of the effects of fresh residues on the predatory mite, Typhlodromus pyri (Acari: Phytoseiidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-41 GLP not published Syngenta File No A12739A_10010			R-25/2009	
KCP 10.3.2 / 02	Stevens J.	2012	Mesotrione SC (A12739A) - A rate-response laboratory bioassay of the effects of fresh residues on the parasitic wasp Aphidius rhopalosiphii (Hymenoptera, Braconidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-12-42 GLP not published Syngenta File No A12739A_10008	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.3.2 / 03	Fallowfield L.	2013	Mesotrione SC (A12739A) - A rate-response extended laboratory bioassay of the effects of fresh residues on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-4 GLP not published Syngenta File No A12739A_10020	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.3.2 / 04	Stevens J.	2013	Mesotrione SC (A12739A) - A rate-response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp Aphidius rhopalosiphii (Hymenoptera, Braconidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-5 GLP not published Syngenta File No A12739A_10276	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.3.2 / 05	Tew G.	2013	Mesotrione SC (A12739A) - A rate-response extended laboratory test to evaluate the effects of fresh residues on the rove beetle Aleochara bilineata (Coleoptera; Staphylinidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-6 GLP not published	N	Y	Data protection started with: R-25/2009	SYN

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KCP 10.3.2 / 06	Vaughan R.	2013	Syngenta File No A12739A_10275 Mesotrione SC (A12739A) - A rate-response extended laboratory test to determine the effects of fresh residues on spiders of the genus Pardosa (Araneae, Lycosidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-13-7 GLP not published Syngenta File No A12739A_10388	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.4 / 01	Friedrich S.	2011	Mesotrione SC (A12739A) - Sublethal toxicity to the earthworm Eisenia fetida in artificial soil Syngenta - Jealott's Hill, Bracknell, United Kingdom BioChem Agrar, Gerichshain, Germany, 11 10 48 003 S GLP not published Syngenta File No A12739A_10000	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.4 / 02	Friedrich S.	2013	Mesotrione SC (A12739A) - Effects on the Reproduction of the Collembolan Folsomia candida Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 009 S GLP not published Syngenta File No A12739A_10013	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.4 / 03	Schulz L.	2013	Mesotrione SC (A12739A) - Effects on the Reproduction of the Predatory Mite Hypoaspis aculeife Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 010 S GLP not published Syngenta File No A12739A_10014	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.5 / 01	Schulz L.	2014	Mesotrione SC (A12739A) - Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests) Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 13 10 48 006 C/N GLP not published Syngenta File No A12739A_10024	N	Y	Data protection started with: R-25/2009	SYN
KCP 10.6 /	Porch J., Martin	2003	ZA1296 (Mesotrione): The toxicity effects of a 100 g/litre SC	N	Y	Data protection started with:	SYN

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01	K., Krueger H.		formulation (A12739A) on the seedling emergence of ten species of plants Syngenta Crop Protection AG, Basel, Switzerland Wildlife International Ltd., Easton MD, USA, 528-152 GLP not published Syngenta File No ZA1296/1144			R-25/2009	
KCP 10.6 / 02	Porch J., Martin K., Krueger H.	2003a	ZA1296 (Mesotrione): The toxicity effects of a 100 g/litre SC formulation (A12739A) on the vegetative vigour of ten species of plants Syngenta Crop Protection AG, Basel, Switzerland Wildlife International Ltd., Easton MD, USA, 528-153 GLP not published Syngenta File No ZA1296/1145	N	Y	Data protection started with: R-25/2009	SYN

The following tables are to be completed by MS

#### 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-

#### List of data relied on and 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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
-	-	-	-	-	-	-	-

