REGISTRATION REPORT

Part A

Risk Management

Product code: MEZI 100 SC

Product name(s): Rumezo Twist 100 SC,
Malton Twist 100 SC

Chemical active substance(s):
Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization**)**

Applicant: Innvigo Sp. z o.o.

Submission date: December 2023, October 2024

RMS Assessment: 24/07/2024

Following commenting period: 21/10/2024

zRMS correction: 16.12.2024

Final version: 18.12.2025

Version history

When	What
July 2024	zRMS assessment
October 2024	Following commenting period
October 2024	Applicant update
December 2024	zRMS correction
December 2025	Final version

Table of Contents

PART A
RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions required for zonal registration of MEZI 100 SC (Rumezo Twist 100 SC, Malton Twist 100 SC) containing Mesotrione in Poland (ZRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 0-10 and Part C. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review It also includes assessment of data and information relating to MEZI 100 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of MEZI 100 SC have been made using endpoints agreed in the EU review of MEZI 100 SC.

This document describes the specific conditions of use and labelling required for the registration of (Rumezo Twist 100 SC, Malton Twist 100 SC) product code MEZI 100 SC..

1.1 Application background

This application was finalized by Innvigo Sp. z o.o. in May 2020. Innvigo Sp. z o.o. is a company located at Aleje Jerozolimskie 178, 02-486 Warsaw, Poland and registered in the Polish National Court Registry of entrepreneurs (KRS), with the number 0000540684 r .

The application is for the approval of MEZI 100 SC a suspension concentrate type formulation (SC) containing 100 g/L Mesotrione for use as a herbicide in Maize. It is a applied by spray once per season:
- maize: once per season at BBCH 14-15.

To obtain authorisation the product MEZI 100 SC must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed endpoints.

This application was submitted in order to allow the first authorisation of this product in Poland, in accordance with the above.

1.2 Letters of Access

Not relevant

1.3 Justification for submission of tests and studies

In accordance with Art. 33 (3), the submitted studies and presented in Appendix 4, are relevant and necessary to obtain the first authorisation the product MEZI 100 SC in Poland and other countries.

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.

In accordance with Art. 33(3), the submitted studies and presented in Appendix 4, are relevant and necessary to obtain the first authorisation the product MEZI 100 SC in Poland and other countries.

In accordance with Art. 34 Regulation (EC) 1107/2009, the documentation refers to studies and tests presented in documentation of MEZI 100 SC, for which the data protection has expired.

Callisto 100 S.C. is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for registration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document.

2 Details of the authorization decision

2.1 Product identity

Product code	MEZI 100 SC
Product name in MS	Rumezo Twist 100 SC, Malton Twist 100 SC
Authorization number	N/D
Function	Herbicide
Applicant	Innvigo Sp. z o.o.
Active substance(s) (incl. content)	Mesotrione 100 g/L
Formulation type	Suspension concentrate [Code: SC]
Packaging	professional user 250 ml HDPE bottle 500 ml HDPE bottle 510 ml HDPE jar 564 ml HDPE bottle 600 ml HDPE bottle 800 ml HDPE jar/bottle 1000 ml HDPE bottle 1200 ml HDPE bottle 2000 ml HDPE jar/bottle 3000 ml HDPE container 4000 ml HDPE cannister 5000 ml HDPE bottle/container/cannister 5850 ml HDPE container 6000 ml HDPE cannister 10000 ml HDPE container/cannister 11220 ml HDPE container 20000 ml HDPE container/cannister 22000 ml HDPE container

	According to guideline from Ministry of Agriculture and Rural Development (*Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin*) storage stability study can be extrapolated to new packaging material HDPE/PA, HDPE/F, HDPE/EvOH from provided and evaluated storage stability studies of packing HDPE. Therefore, no further studies are required for the additional packaging materials. 275 ml HDPE/PA bottle 323 ml HDPE/PA bottle 574 ml HDPE/PA bottle 550 ml HDPE/PA bottle 1000 ml HDPE/PA bottle 1100 ml HDPE/PA bottle 5000 ml HDPE/PA bottle, cannister 5500 ml HDPE/PA bottle 5850 ml HDPE/PA container 10000 ml HDPE/PA container 312 ml HDPE/F bottle 318 ml HDPE/F bottle 570 ml HDPE/F bottle 575 ml HDPE/F bottle 580 ml HDPE/F bottle 585 ml HDPE/F bottle 1150 ml HDPE/F bottle 1160 ml HDPE/F bottle 1170 ml HDPE/F bottle 1185 ml HDPE/F bottle 1200 ml HDPE/F bottle 5880 ml HDPE/F cannister 5950 ml HDPE/F bottle/cannister 10000 ml HDPE/F cannister 250 ml HDPE/EVOH bottle 310 ml HDPE/EVOH bottle 500 ml HDPE/EVOH bottle 579 ml HDPE/EVOH bottle 1000 ml HDPE/EVOH bottle 1200 ml HDPE/EVOH bottle 5000 ml HDPE/EVOH container 5650 ml HDPE/EVOH cannister 10000 ml HDPE/EVOH container 20000 ml HDPE/EVOH container
Coformulants of concern for national authorizations	N/A
Restrictions related to identiy	N/A
Mandatory tank mixtures	N/A
Recommended tank mixtures	N/A

2.2 Conclusion

No conclusions.
The evaluator also verified whether the co-formulants contained in plant protection product MEZI 100 SC (Product name(s): Rumezo Twist 100 SC, Malton Twist 100 SC) are listed in Annex III to Regulation

(EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.
Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product MEZI 100 SC (Product name(s): Rumezo Twist 100 SC, Malton Twist 100 SC) does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.
According to the current knowledge and available information none of the co-formulants in the plant protection product MEZI 100 SC (Product name(s): Rumezo Twist 100 SC, Malton Twist 100 SC) meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products, except one ingredient of one co-formulant.
Taking this into account, one of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

2.3 Substances of concern for national monitoring

This point is not relevant for authorisation of MEZI 100 SC.

2.4 Classification and labelling

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

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Eye irrit. 2 Repr. 2 Acute aquatic toxicity Category 1 Chronic aquatic toxicity Category 1

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 or Code(s) for hazard pictogram(s):	
Signal word:	**Warning**
Hazard statement(s):	**H319 Causes serious eye irritation** **H361d Suspected of damaging the unborn child** **H410 Very toxic to aquatic life with long lasting effects.**
Precautionary statement(s):	**P202 Do not handle until all safety precautions have been read and understood.** **P280 Wear protective gloves/protective clothing/eye protection/face protection.** **P308+P313 IF exposed or concerned: Get medical advice/attention.** **P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **P337 + P313 If eye irritation persists: Get medical advice/ attention.** **P391 Collect spillage.** **P405 Store locked up.**
Additional labelling phrases:	**To avoid risks to man and the environment, comply with the instructions for use. [EUH401]**

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
SPe3	To protect aquatic organisms respect an 10 meters of vegetative buffer zone to surface water bodies

See Part B and C for justifications of the classification and labelling proposals.

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

SP 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).
SPe3	

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

	N/A

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:	
N/A	"Wear protective gloves, eye/face protection and work wear during mixing and loading and application"
Worker protection:	
N/A	"Wear protective workwear"
Integrated pest management (IPM)/sustainable use:	
N/A	The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
N/A	For the protection of aquatic organisms in intended use of product MEZI 100 SC following limitations are necessary to maintain : • For Poland, are necessary to maintain the 10 meters of vegetative buffer zone and 10 meters of no-spray zone for all pH values.
Other specific restrictions	
N/A	No other specific restrictions

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

Integrated pest management (IPM)/sustainable use:	
N/A	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorization is applied.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
respective code if available	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.	use number from GAP table in 2.6
Environmental protection:		Relevant for use no.
respective code if available	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed.	use number from GAP table in 2.6

2.6 Intended uses (only NATIONAL GAP)

GAP rev. , date: 2023-05-26

PPP (product name/code):	MEZI 100 SC	Formulation type:	SC [a, b]
Active substance 1:	mesotrione	Conc. of as 1:	100 g/L[c]
Active substance 2:	-	Conc. of as 2:	- [c]
Active substance 3:	-	Conc. of as 3:	- [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	Innvigo Sp. z o.o.	Professional use:	☒
Zone(s):	Central [d]	Non professional use:	☐
Verified by MS:	No		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	15	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Re-marks:** e.g. g safen-er/synerg ist per ha [f]	ZRMs Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between appli-cations (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Maize *Zea mays* ZEAMX	F	Mono- and dicotyle-donous weeds	Spray, medium sprayer	BBCH 14-15	a) 1 b) 1	n/a	a) 1.0 L/ha b) 1.0 L/ha	a) 100 g as/ha b) 100 g as/ha	200-300	n/a	-	
2														
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
3														
4														

Minor uses according to Article 51 (zonal uses)														
5														
6														
Minor uses according to Article 51 (interzonal uses)														
7														
8														

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph nº2, 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 and light-brown liquid with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has not a flash point It has a self-ignition temperature of 376°C. In aqueous solution, it has a pH value around 2.75 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 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 material. Its technical characteristics are acceptable for a SC formulation.

3.2 Efficacy (Part B, Section 3)

The applicant submitted 3 reports (in total) showing the results in research into product efficacy carried out in 2023 in Poland in maize. List of these reports is contained in Appendix 4. Trials were carried out in one season because this herbicide contains mesotrione which is a well-known active substance that has been used for many years in agricultural practice.
The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:

- PP 1/135 (3) Phytotoxicity assessment
- PP 1/152 (4) Design and analysis of efficacy evaluation trials
- PP 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice
- PP 1/50(4) Weeds in maize

They were carried out on the field in the conditions of natural weeds infestation.
The product MEZI 100 SC has been used in maize at the following rates of:
1.0 L/ha – postemergence BBCH 14-15.
Callisto 100 SC was used as a reference product in maize.

3.3 Efficacy data

The applicant submitted 3 reports in total showing the results in research into product efficacy carried out in 2023 in maize.

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

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

The following table describes the effectiveness of weeds

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

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

Product code (L, kg/ha)	EPPO code	Scientific name	DA-A	Pest stage	Average	Efficacy
MEZI 100 SC	CHEAL	*Chenopodium album*	14 DA-A	BBCH 12-35	87.67	S
	ECHCG	*Echinochola crus-galli*	14 DA-A	BBCH 12-23	71.20	MS
	POLCO	*Polygonum convovulus*	14 DA-A	BBCH 12-21	75.47	MS
	POLPE	*Polygonym persicaria*	14 DA-A	BBCH 12-18	76.45	MS
	GAETE	*Galeopsis tetrahit*	14 DA-A	BBCH 12-21	84.30	MS
	GASPA	*Galisnoga parviflora*	14 DA-A	BBCH 13-14	85.00	S
	CAPBP	*Capsella bursa-pastoris*	14 DA-A	BBCH 13-22	83.95	MS
	SETPU	*Setaria pumila*	14 DA-A	BBCH 13-21	0.00	T
Callisto 100 SC	CHEAL	*Chenopodium album*	14 DA-A	BBCH 12-35	90.40	S
	ECHCG	*Echinochola crus-galli*	14 DA-A	BBCH 12-23	74.07	MS
	POLCO	*Polygonum convovulus*	14 DA-A	BBCH 12-21	79.30	MS
	POLPE	*Polygonym persicaria*	14 DA-A	BBCH 12-18	79.65	MS
	GAETE	*Galeopsis tetrahit*	14 DA-A	BBCH 12-21	84.30	MS
	GASPA	*Galisnoga parviflora*	14 DA-A	BBCH 13-14	88.60	S
	CAPBP	*Capsella bursa-pastoris*	14 DA-A	BBCH 13-22	83.60	MS
	SETPU	*Setaria pumila*	14 DA-A	BBCH 13-21	0.00	T

On the basis of submitted research, it is possible to state that the MEZI 100 SC controlled maize at level:
MEZI 100 SC 1.0 L/ha
Susceptible: *Chenopodium album*, *Galisnoga parviflora*
Moderately Susceptible: *Echinochola crus-galli, Polygonum convovulus, Polygonym persicaria, Galeopsis tetrahit, Capsella bursa-pastoris*
Tolerant: *Setaria pumila*

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

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

On the basis of submitted research, it is possible to state that the MEZI 100 SC controlled maize at level:
MEZI 100 SC 1.0 L/ha
Susceptible: *Chenopodium album*, *Galisnoga parviflora, Polygonum convovulus, Polygonym persicaria, Galeopsis tetrahit, Capsella bursa-pastoris*
Moderately Susceptible: *Echinochola crus-galli,*
Tolerant: *Setaria pumila*

The carried out trials confirm that MEZI 100 SC has the same high efficacy as Callisto 100 SC against the same weed spectrum.
Details will be provided in the dRR Part B Section 3 KCP 6 point 3.2.

In all bridging trials, the efficacy of the product tested was comparable to the reference product Callisto 100 SC. The both products in the bridging trials showed comparable efficacy against dicots in comparison to the efficacy of dicots weeds presented on the reference product label (Callisto 100 SC). What is more, both products showed lower efficacy against ECHCG (28 DAA, 3 trials), compared to ECHCG susceptibility classification presented on the label currently authorised reference product Callisto 100 SC (the only monocotyledonous weed species included on the reference product label).
It is proposed to include the ECHCG classification on the MEZI 100 SC label according to the results of the bridging trials presented (MS) and placed classification of the dicots weeds as it is presented on the reference product label.

In all bridging trials, the efficacy of the product tested was comparable to the reference product Callisto 100 SC. Unprotected data of Callisto 100 SC can be used to support the authorisation of MEZI 100 SC.

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

Mesotrione belongs to the chemical group of the triketones (2-benzylcyclohexane-1,3-diones), which acts by blocking the function of the essential plant enzyme 4-hydroxy-phenyl-pyruvatedioxygenase (4-HPPD) in the cytosol of sensitive plants. Mesotrione is a systemic herbicide and controls most annual broadleaf and annual grass weed species in maize. It is taken up via roots and shoots and translocated rapidly in both the xylem and phloem into all plant parts. In sensitive plants symptoms of white chlorosis become visible within a few days after application in actively growing tissues being in the cell elongation phase. Complete death of sensitive plants may occur up to 2 weeks after application. Maize has a natural tolerance against mesotrione as it can detoxify the herbicide into inactive compounds. This detoxification is mediated by cytochrome-P450-oxygenase and is so rapid in maize that mesotrione is not translocated away from the treated zone to the point of action. Sensitive weed species cannot detoxify mesotrione in this way. Mesotrione belongs to HRAC group 27 (Legacy F2). According to Ian Heap's website (http://www.weedscience.org) there are only three species which have been reported as resistant to HRAC group 27 (Legacy F2). These are *Amaranthus palmeri*, *Amaranthus tuberculatus* (=*A. rudis*) and *Raphanus raphanistrum*. All cases reported have been in the United States and Australia with no evidence of resistance in Europe.
According to submitted efficacy data none of the tested weeds showed high tolerance to the product MEZI 100 SC.
According to EPPO PP 1/213 (4) Resistance risk analysis weeds usually only produce one generation per year and development of resistance is usually a relatively slow process.
In conclusion, in the applicant's opinion, this level of weeds resistance risk should be considered to be acceptable.
Details will be provided in the dRR Part B Section 3 KCP 6.3 point 3.3.

3.3.2 Adverse effects on treated crops

The applicant submitted 3 reports (in total) showing the results in research into product efficacy carried out in 2023 in Poland in maize. List of these reports is contained in Appendix 4. Trials were carried out in one season because this herbicide contains mesotrione which is a well-known active substance that has been used for many years in agricultural practice.
The 3 efficacy trials in maize were carried out in Poland in 2023 on a wide range of commercially grown varieties. There were not observed any phytotoxicity symptoms on tested product and standard in trials.

Details will be provided in the dRR Part B Section 3 KCP 6.4 point 3.4.

3.3.3 Observations on other undesirable or unintended side-effects

Undesirable effects are not expected on succeeding crops, adjacent crop, part of plants used for propagating purposes and beneficial organisms.
Details will be provided in the dRR Part B Section 3 KCP 6.5 point 3.5.

3.4 Methods of analysis (Part B, Section 5)

Analytical methods for determination of Mesotrione impurities and relevance of CIPAC methods in MEZI 100 SC were not evaluated as part of the EU review of Mesotrione . Therefore all relevant data are provided and are considered adequate.

3.4.1 Analytical method for the formulation

The method for determination of active substances in Mesotrione preparation is specific. The validation parameters for linearity, instrument precision, repeatability and accuracy are within the acceptance range.

3.4.2 Analytical methods for residues

The methods was successfully validated for determination of all analytes in most of matrices with an LOQ of 0.01 mg/kg according to the guidance document(s) SANCO/3029/99 rev. 4.
With regard to selectivity, accuracy and precision, the analytical methods were applied successfully for each analytical set when analysing the specimens of the study

3.5 Mammalian toxicology (Part B, Section 6)

Based on data provided, product MEZI 100 SC (Product name(s): Rumezo Twist 100 SC, Malton Twist 100 SC) should be classified as Eye Irrit. 1 H319 and Repr. 2 H361d. Based on hazard classification it is recommended to wear suitable protective clothing, protective gloves and safety glasses or face protection during mixing/loading and application. According to model calculations, it can be concluded that the risk of worker exposure during re-entry activities on area treated with MEZI 100 SC/ Rumezo Twist 100 SC, Malton Twist 100 SC is acceptable when the workwear (long sleeved shirt, long trousers) is worn.

3.5.1 Acute toxicity

In vivo acute toxicity studies including irritancy and skin sensitisation with reference product Callisto 100 SC have been evaluated as the representative formulation in the EU review of mesotrione. The studies

have been reviewed and accepted during EU review of mesotrione and registration process of Calisto 100 SC in Poland. According to current requirements the studies are acceptable for toxicological evaluation of MEZI 100 SC.
A summary of the acute toxicological evaluation for product MEZI 100 SC (Product name(s): Rumezo Twist 100 SC, Malton Twist 100 SC) is given in the following table:

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)
LD_{50} oral, rat (OECD 425)	> 2000 mg/kg bw	Yes*	None
LD_{50} dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes*	None
LC_{50} inhalation, rat** (OECD 403)	Waiver submitted	Yes*	None
Skin irritation, rabbit (OECD 404)	Non-irritant	Yes*	None
Eye irritation, rabbit (OECD 405)	Irritant	Yes**	H319
Skin sensitisation, guinea pig (OECD 406)	Non-sensitising	Yes	None

* Studies have been reviewed and accepted during EU review of active substance and previous registration process of Callisto 100 SC, zRMS:PL did not performed a new assessment.
** No acute inhalation study was conducted, waiver reviewed and accepted during EU review of active substance and previous registration process of Callisto 100 SC, zRMS:PL did not performed a new assessment.

Table 6.1 3: Summary of risk assessment for operators, workers, bystanders and residents for Mesotrione in MEZI 100 SC/ Rumezo Twist 100 SC, Malton Twist 100 SC

	Result	PPE / Risk mitigation measures
Operators	Acceptable	None
Workers	Acceptable	Workwear
Bystanders	Acceptable	None
Residents	Acceptable	None

3.5.2 Operator exposure

According model calculations, it can be concluded that the risk of operator exposure during mixing & loading and application of MEZI 100 SC/ Rumezo Twist 100 SC, Malton Twist 100 SC using the tractor-mounted on field on maize is acceptable in the absence of PPP.
Due to the fact that the product is classified as Repr. 2 H361d and Eye Irrit. 1 H319, the operator should wear workwear, gloves and protective googles or face protection during mixing/loading and application operations.

3.5.3 Worker exposure

According to model calculations, it can be concluded that the risk of worker exposure during re-entry activities on area treated with MEZI 100 SC/ Rumezo Twist 100 SC, Malton Twist 100 SC is acceptable under conditions of intended use when the work wear (long sleeved shirt, long trousers) is worn.
As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.5.4 Bystander and resident exposure

According to model calculations, it can be concluded that there is no unacceptable risk to any resident (child and adult) and bystander after application of MEZI 100 SC/ Rumezo Twist 100 SC, Malton Twist 100 SC on maize.

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

For the use proposed for Mesotrione in MEZI 100 SC, all relevant residue data and assessments are provided. No new data are submitted in the framework of this application.

All magnitude of residue studies are provided and summarized. All data have been evaluated in the EU review of Mesotrione.

The data submitted show that no detectable residues are expected in treated crops and no exceedance of the MRL will occur. The proposed uses are considered acceptable.

Livestock animals are not exposed to residues via feed above the trigger value established in Reg. (EC) No 1107/2009. Feeding studies are therefore not required. Considering the low levels of residues expected in livestock feed commodities from the crops and associated GAP supported in this submission along with extrapolation of residue results from the livestock nature or residue studies in goats and hens, residues of Mesotrione in edible tissues, milk or eggs are not expected to be quantifiable above 0.01 mg/kg.

3.6.1 Consumer exposure

Table 7.2-16: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo ver 3.1	7 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo ver 3.1	Not required
IESTI (% ARfD) according to EFSA PRIMo* ver 3.1	Maize :1 % Maize 0.1%
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of Mesotrione in the MEZI 100 SC do not represent unacceptable acute and chronic risks for the consumer.

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

No new studies are presented; all data were reviewed in the EU review of Mesotrione. Appropriate endpoints from the EU review were used to calculate PECs for MEZI 100 SC, Mesotrione, and its metabolites in soil, surface water, ground water and air for the intended use patterns

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The PECsoil of Mesotrione and its metabolites in soil have been assessed with the DT50 values established in the EU review. Based on the recommended use rate of 1L [product]/ha (1098 g prod/ha).

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

According to PECgw modelling with FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5, FOCUS MACRO 5.5.4 a ground water contamination of the active substance Mesotrione at a concentration of ≥ 0.1 µg/L is not expected in use in Maize crop. For the metabolites a groundwater concentration of ≥ 0.1 µg/L can be excluded.
Assessment of relevance of ground water metabolites is performed and presented in section 10 of dRR.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

PECsw/sed values were calculated for mesotrione and its metabolites MNBA, AMBA and SYN546974.

FOCUS Step1-2 calculations were performed with model STEPS 1-2 v3.2 for mesotrione and all metabolites listed above. In addition, FOCUS Step 3 and 4 calculations were performed for mesotrione. The models of the SWASH shell FOCUS SWASH v5.3 were applied for the calculations. All FOCUS scenarios applicable to maize were executed (D3, D4, D5, D6, R1, R2, R3 and R4). Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) have been calculated for mesotrione and its metabolites after the application of the product MEZI 100 SC on maize:
- 1x 1l product MEZI 100 SC /ha;
considering the pathways spray drift, drainage and runoff. In addition, for the active substance, $PECsw/_{SED}$ values were calculated for a dose of 50g a.s./ha.

PECsw values were calculated for the formulation: MEZI 100 SC.

The results are used for the ecotoxicological evaluation of aquatic organisms.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

MEZI 100 SC no pose any unacceptable risk for birds and mammals according to label.

3.8.2 Effects on aquatic species

Basic on RAC=0.77µg/L from *L.gibba* study available in EFSA Journal 2016;14(3):4419 for the protection of aquatic organisms in intended use of product MEZI 100 SC following limitations are necessary to maintain :

- For Poland are necessary to maintain the 10 meters of vegetative buffer zone and 10 meters of no-spray zone for all pH values.

After redefinition of the risk assessment for aquatic organisms which based on the changing of the RAC values from RAC=0.77µg/L to RAC=2.41µg/L for the protection of aquatic organisms in intended use of product MEZI 100 SC are necessary to maintain: 10 meters vegetative buffer zone and 10 meters no-

spray zone for uses in all available pH values.

The calculated PEC/RAC ratios for the Mesotrione metabolites indicate an acceptable risk for all groups of aquatic organism for the intended uses in Maize, based on FOCUS Step 1 PECSW calculations. No further assessment is necessary for the relevant metabolites of Mesotrione.

The calculated PEC/RAC ratios for formulation indicate an acceptable risk for all groups of aquatic organism for the intended uses in Maize, when 5 m buffer zone is applied.

3.8.3 Effects on bees

MEZI 100 SC no pose any unacceptable risk for bees according to label.

3.8.4 Effects on other arthropod species other than bees

All hazard quotients (HQ) are considerably less than trigger values, indicating that MEZI 100 SC applied at the maximum use rate poses no risk to non-target arthropods. No risk mitigation needed.

3.8.5 Effects on soil organisms

MEZI 100 SC pose no unacceptable risk to non-target soil meso- and macrofauna.

3.8.6 Effects on non-target terrestrial plants

MEZI 100 SC pose an unacceptable risk for non-target terrestrial plants according to label. This product can be used on non-target terrestrial plants only with 50m buffer strip or 5m buffer strip and 90% nozzle reduction.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Tests on other non-target species are not required.

3.9 Relevance of metabolites (Part B, Section 10)

See dRR section B10.

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

As a conclusion of the comparative assessment, use 1 (see GAP table in 2.6) is not suitable for substitution because there is only 1alternative mode of action available amongst alternative products and thus the chemical diversity remaining is not sufficient to minimise the occurrence of resistance.
.

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

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

Appendix 2 Copy of the product label

Załącznik do zezwolenia MRiRW nr R - / z dnia r.

Posiadacz zezwolenia:
Innvigo Sp. z o.o., Al. Jerozolimskie 178, 02-486 Warszawa, tel.: 22 4682670, e-mail: biuro@innvigo.com

RUMEZO TWIST 100 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
mezotrion (związek z grupy związek z grupy trójketonów) - 100 g/l (9,13%)

Zezwolenie MRiRW nr R – / z dnia r.

Uwaga	
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, 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 styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P337 + P313	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady /zgłosić się pod opiekę lekarza
P391	Zebrać wyciek.
P405	Przechowywać pod zamknięciem

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany nalistnie, w postaci koncentratu w formie stężonej zawiesiny do rozcieńczania wodą (SC).
Zgodnie z klasyfikacją HRAC substancja czynna mezotrion zaliczana jest do grupy 27 (dawniej F2).

DZIAŁANIE NA CHWASTY
Środek zawiera substancję czynną zaliczaną do inhibitorów biosyntezy karotenoidów, powodującą zniszczenie chlorofilu, objawiające się bieleniem liści.
Środek pobierany jest głównie poprzez liście oraz dodatkowo poprzez korzenie chwastów i szybko przemieszczany w roślinie, hamując ich wzrost i rozwój.
Pierwsze objawy działania środka widoczne są po 5-7 dniach od wykonania zabiegu. Zamieranie chwastów następuje po około 14 dniach.
Środek stosować po wschodach chwastów w okresie, gdy mają one rozwinięte 2-6 liści. Środek najskuteczniej działa na chwasty w fazie 4-tego liścia.

Chwasty wrażliwe:	fiołek polny, gwiazdnica pospolita, jasnota purpurowa, komosa biała, przytulia czepna, rdestówka powojowata (syn. rdest powojowaty), rumian polny, szarłat szorstki, tasznik pospolity, tobołki polne, żółtlica drobnokwiatowa.
Chwasty średniowrażliwe:	dymnica pospolita, chwastnica jednostronna

STOSOWANIE ŚRODKA
Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Kukurydza
Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 1,0 l/ha.
Termin stosowania: środek stosować w fazie 4-5 liści kukurydzy (BBCH 14-15).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Zalecana ilość wody: 200-300 l/ha.
Zalecane opryskiwanie: średniokropliste

NASTĘPSTWO ROŚLIN
W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na polu można uprawiać kukurydzę lub życicę trwałą. Po wykonaniu głębokiej orki oprócz w/w roślin można także uprawiać sorgo.
Po zbiorze kukurydzy uprawianej w normalnych warunkach wegetacji, odchwaszczonej środkiem Rumezo Twist 100 SC 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, gleba nadmiernie ugnieciona) 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, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA
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 odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:
– postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, 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 mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
– stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (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 wraz z objętością środka. Zawartością opakowania przed użyciem wstrząsnąć. 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. Uzupełnić wodą do potrzebnej ilości. Opryskiwać z włączonym mieszadłem. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego 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
Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:
– jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg 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 wymyć oraz przepłukać trzykrotnie wodą.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

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

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

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

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.

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 niezgodnego z przeznaczeniem uwalniania do środowiska.
W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 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:

- 50 m lub
- 5 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej
  - podczas zabiegu o 90%

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz
  - dostęp osób trzecich,
- 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 dostania się do oczu: ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady /zgłosić się pod opiekę lekarza.

Okres ważności – 2 lata.

Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Załącznik do zezwolenia MRiRW nr R - / z dnia r.

Posiadacz zezwolenia:
Innvigo Sp. z o.o., Al. Jerozolimskie 178, 02-486 Warszawa, tel.: 22 4682670, e-mail: biuro@innvigo.com

MALTON TWIST 100 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
mezotrion (związek z grupy związek z grupy trójketonów) - 100 g/l (9,13%)

Zezwolenie MRiRW nr R – / z dnia r.

Uwaga	
H319 H361d H410	Działa drażniąco na oczy. Podejrzewa się, że działa szkodliwie na dziecko w łonie matki. 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 P280	Nie używać przed zapoznaniem się i zrozumieniem wszystkich środków bezpieczeństwa. Stosować rękawice ochronne, odzież ochronną, 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 styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P337 + P313	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady /zgłosić się pod opiekę lekarza
P391	Zebrać wyciek.
P405	Przechowywać pod zamknięciem

OPIS DZIAŁANIA
HERBICYD selektywny o działaniu układowym, stosowany nalistnie, w postaci koncentratu w formie stężonej zawiesiny do rozcieńczania wodą (SC).
Zgodnie z klasyfikacją HRAC substancja czynna mezotrion zaliczana jest do grupy 27 (dawniej F2).

DZIAŁANIE NA CHWASTY
Środek zawiera substancję czynną zaliczaną do inhibitorów biosyntezy karotenoidów, powodującą zniszczenie chlorofilu, objawiające się bieleniem liści.
Środek pobierany jest głównie poprzez liście oraz dodatkowo poprzez korzenie chwastów i szybko przemieszczany w roślinie, hamując ich wzrost i rozwój.
Pierwsze objawy działania środka widoczne są po 5-7 dniach od wykonania zabiegu. Zamieranie chwastów następuje po około 14 dniach.
Środek stosować po wschodach chwastów w okresie, gdy mają one rozwinięte 2-6 liści. Środek najskuteczniej działa na chwasty w fazie 4-tego liścia.

Chwasty wrażliwe:	fiołek polny, gwiazdnica pospolita, jasnota purpurowa, komosa biała, przytulia czepna, rdestówka powojowata (syn. rdest powojowaty), rumian polny, szarłat szorstki, tasznik pospolity, tobołki polne, żółtlica drobnokwiatowa.
Chwasty średniowrażliwe:	dymnica pospolita, chwastnica jednostronna

STOSOWANIE ŚRODKA
Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Kukurydza
Maksymalna/zalecana dawka środka dla jednorazowego zastosowania: 1,0 l/ha.
Termin stosowania: środek stosować w fazie 4-5 liści kukurydzy (BBCH 14-15).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.
Zalecana ilość wody: 200-300 l/ha.
Zalecane opryskiwanie: średniokropliste

NASTĘPSTWO ROŚLIN
W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na polu można uprawiać kukurydzę lub życicę trwałą. Po wykonaniu głębokiej orki oprócz w/w roślin można także uprawiać sorgo.
Po zbiorze kukurydzy uprawianej w normalnych warunkach wegetacji, odchwaszczonej środkiem Malton Twist 100 SC 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, gleba nadmiernie ugnieciona) 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, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA
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 odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:
– postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, 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 mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
– stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (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 wraz z objętością środka. Zawartością opakowania przed użyciem wstrząsnąć. 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. Uzupełnić wodą do potrzebnej ilości. Opryskiwać z włączonym mieszadłem. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego 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
Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:
– jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg 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 wymyć oraz przepłukać trzykrotnie wodą.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH
Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

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

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

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.

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 niezgodnego z przeznaczeniem uwalniania do środowiska.
W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 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:
- 50 m lub
- 5 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej
  - podczas zabiegu o 90%

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA
Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz
  - dostęp osób trzecich,
- 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 dostania się do oczu: ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady /zgłosić się pod opiekę lekarza.

Okres ważności – 2 lata.
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Letter of Access

Appendix 4 Lists of data considered for national authorization

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.2 KCP 2.6.1 KCP.2.7.3 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 5.1.1/01	Arévalo E.,	2021	CHR/H/MEZZO 100 SC Determination of physicochemical properties of the preparation Study code: BF-49/20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	Y	Data never submitted before to PL	Chemirol
KCP 2.2.1	Ołowski G.,	2023	MEZI 100 SC Determination of explosive properties Study code: BW-07/23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	Y	Data never submitted before to PL	Chemirol
KCP 2.2.2 KCP 2.3.1 KCP 2.3.3	Pachnicki P.	2023	MEZI 100 SC Determination of flash point, auto-ignition temperature and oxidizing properties Study code: BC-31/23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry GLP Unpublished	N	Y	Data never submitted before to PL	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2	Eliza Potocka	2023	Efficacy and selectivity of MEZI 100 SC (mesotrione 100 g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz, Poland Report no: **EU-23-1560-PL01** GEP – yes Unpublished	N	Y	Data never submitted before to PL	Chemirol
KCP 6.2	Eliza Potocka	2023	Efficacy and selectivity of MEZI 100 SC (mesotrione 100 g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz, Poland Report no: **EU-23-1560-PL02** GEP – yes Unpublished	N	Y	Data never submitted before to PL	Chemirol
KCP 6.2	Eliza Potocka	2023	Efficacy and selectivity of MEZI 100 SC (mesotrione 100 g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz, Poland Report no: **EU-23-1560-PL03** GEP – yes Unpublished	N	Y	Data never submitted before to PL	Chemirol
KCP 5.2/01	Zaworska K.,	2023	Validation of analytical method for determination of active substance (mesotrione) of the test item MEZI 100 SC in 50% (w/v) sucrose solution Study code: 0038/0177/FA SORBOLAB Research Laboratory LLC GLP: yes unpublished	N	Y	Data never submitted before to PL	Chemirol
KCP 5.2/02	Ciorga B.,	2023	Validation of analytical method for determination of active substance (mesotrione) of the test item MEZI 100 SC in deionized water	N	Y	Data never submitted before to PL	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Study code: 0038/0175/FA SORBOLAB Research Laboratory LLC GLP: yes unpublished				
KCP 10.3.1	Zaworska K	2023	Honey bee, chronic oral toxicity test of test item MEZI 100 SC Study code: 0038/0178/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data never submitted before to PL	Chemirol
KCP 10.3.1	Woźniak A.	2023	Honey bee larval toxicity test following repeated exposure of the test item MEZI 100 SC Study code: 0038/0176/E SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	Data never submitted before to PL	Chemirol
KCP 10.6.2	Czarnynoga M.	2023	MEZI 100 SC: Terrestial Plant Test: Vegetative Vigour Test Study code: G-50-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group GLP Unpublished	N	Y	Data never submitted before to PL	Chemirol
KCP 10.6.2	Czarnynoga M.	2023	MEZI 100 SC Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test Study code: G-51-23 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Ecotoxicology Research Group GLP Unpublished	N	Y	Data never submitted before to PL	Chemirol

List of data submitted by the applicant and relied on, but evaluated before in Callisto 100 SC

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2 KCP 2.3	Jackson W.	2017	A12739A - Safety Study Syngenta Crop Protection AG, Basel, Switzerland Syngenta Technology & Engineering, Huddersfield UK, HT17/506 GLP not published Syngenta File No A12739A_11137	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 2.7	Fumeaux J.	2014	A12739A - Storage Stability and Shelf Life Statement (2 Years 20 -C) in Packaging Made of HDPE Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Munchwilen, Switzerland, 300022324 Not GLP not published Syngenta File No A12739A_10499	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 5.1.1	Hager M.	2011	R287431 - Analytical Method SD-977/2 Syngenta Crop Protection AG, Basel, Switzerland Syngenta File No R287431_10003, Report No. Syngenta Crop Protection, LLC, Greensboro, NC, USA, 10427012 Not GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
						fers to above mentioned studies within this document	
KCP 5.1.1	Hager M.	2011a	Validation of method SD-977/2 - R287431 in A14203B, A13789C, A14351BX, A12909Q, A15189G, A12738A, A15901A and A18219B Syngenta File No R287431_10001 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, 10427878 GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 5.1.1	Hager M.	2015	A12739A- Statement on Validation of Analytical Method SD-977/2 for Determination of R287431 (Xan-1) in Formulation A12739A (MESOTRIONE SC 100) Syngenta File No A12739A_11032 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300035703 Not GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 5.1.1	Baker, S. *et al*	2018	A12739A- Response to the Danish Regulatory Authority Concerning Relevant Impurity R287431 Syngenta File No A12739A_11278 Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300035703 Not GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
						within this document	
KCP 5.1.1	Huang S.	2016	ZA1296 - SD-1990/1 - Determination of R287432 in Mesotrione Related Formulations by Liquid Chromatography/Mass Spectrometry (LC/MS) Syngenta File No A13789C_50005 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300068727 Not GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document	Syngenta
KCP 5.1.1	Huang S.	2016a	A13789C - Validation of Analytical Method SD-1990/1 Syngenta File No A13789C_50004 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, LLC, Greensboro, NC, USA, USGR160250 GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document	Syngenta
KCP 5.1.1	Huang S.	2016b	A12739A - Statement on Validation of Analytical Method SD-1990/1 for Determination of R287432 in Formulation A12739A (ZA1296 SC (100)) Syngenta File No A12739A_11095 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300072558 Not GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.1	Meyerhoffer W., Zhang Y., Patter-son J.	2016	ZA1296 - SD-1973/1 - Determination of Impurity DCE (1,2-dichloroethane) in Mesotrione Related Formulations by Headspace Gas Chromatography Syngenta File No A13789C_50002 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300066025 Not GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 5.1.1	Meyerhoffer W.	2016	A13789C - Validation of Analytical Method SD-1973/1 Syngenta File No A13789C_50001 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, LLC, Greensboro, NC, USA, USGR160249 GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 5.1.1	Meyerhoffer W.	2016a	A12739A - Statement on Validation of Analytical Meth-od SD-1973/1 for Determination of 1,2-Dichloroethane (DCE) in Formulation A12739A (ZA1296 SC (100)) Syngenta File No A12739A_11096 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, LLC, Greensboro, NC, USA, 300072402 Not GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP	North L.	2016	Mesotrione - Foliage Decline with A12739A on Maize	N	N	Callisto 100 SC is the original	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
5.1.2			in Northern France and the United Kingdom in 2015 Syngenta File No A12739A_11065 Syngenta Crop Protection AG, Basel, Switzerland Eurofins Agroscience Services Ltd, Wilson, UK, S15-02057 GLP Unpublished			product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	
KCP 5.1.2	Hengsberger A., Wydra V.	2015	Mesotrione wet paste (ZA1296) - Toxicity to the aquatic plant Lemna gibba in a reciprocal growth inhibition test Syngenta Crop Protection AG, Basel, Switzerland IBACON GmbH, Rossdorf, Germany, 105731240 GLP Unpublished Syngenta File No ZA1296_10436	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 5.1.2.	Kosak L., Wydra V.	2016	Mesotrione wet paste (ZA1296) - Toxicity to the aquatic plant Lemna gibba in a semi-static growth inhibition test with a subsequent recovery period Syngenta Crop Protection AG, Basel, Switzerland IBACON GmbH, Rossdorf, Germany, 105732240 GLP Unpublished Syngenta File No ZA1296_10438	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 5.1.2.	Gonsior G.	2017	Mesotrione - Growth inhibition of Myriophyllum spi-catum in a water/sediment system	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Syngenta Crop Protection AG, Basel, Switzerland Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S16-06273 GLP Unpublished Syngenta File No ZA1296_10504			o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	
KCP 5.1.2.	Bachelor B.	2014	Analytical Method Transfer and Partial Validation for the Determination of CA3511 in Dosing Formulations Syngenta Crop Protection AG, Basel, Switzerland Syngenta File No CA3511_50013 Xenometrics, LLC, Stilwell, KS, USA, 11070 GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 5.1.2.	Faulkner L., Heap C.	2013	CA3511 - Feasibility of the Assay for the Determination of CA3511 in 1 % w/v Aqueous Carboxymethylcellu-lose Syngenta Crop Protection AG, Basel, Switzerland Sequani Limited, Ledbury, United Kingdom, BFI0147 Not GLP not published Syngenta File No CA3511_10006	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP	Faulkner L., Heap	2013a	CA3511 - Validation of the Assay for the Determination	N	N	Callisto 100 SC is the original	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
5.1.2	C.		of CA3511 in 1 % w/v Aqueous Carboxymethylcellu-lose Syngenta Crop Protection AG, Basel, Switzerland Sequani Limited, Ledbury, United Kingdom, BFI0148 GLP Unpublished Syngenta File No CA3511_10007			product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	
KCP 5.1.2	Faulkner L., Heap C.	2013b	CA3511 - Validation of the Formulation Procedure for CA3511 in 1 % w/v Aqueous Carboxymethylcellulose and Assessment of Formulation Stability Syngenta Crop Protection AG, Basel, Switzerland Sequani Limited, Ledbury, United Kingdom, BFI0149 GLP Unpublished Syngenta File No CA3511_10009	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 5.1.2.	[redacted]	2016	AMBA - Single Dose Oral (Gavage) Proof of Exposure Study in the Rat [redacted] GLP Unpublished [redacted]	Y	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2.	Williams R.	2004	Analytical Method 1200-03 for the Determination of Mesotrione and its Metabolites AMBA and MNBA, in Soil, Using Liquid Chromatography - Electrospray Ionization Tandem Mass Spectrometry (Including Validation Data) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001200-03 GLP Unpublished	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document	Syngenta
KCP 10.1.2.2	North L.	2016	Mesotrione - Foliage Decline with A12739A on Maize in Northern France and the United Kingdom in 2015 Syngenta Crop Protection AG, Basel, Switzerland Eurofins Agroscience Services Ltd, Wilson, UK, S15-02057 GLP not published Syngenta File No A12739A_11065	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies within this document	Syngenta
KCP 10.1.2.2	Grimm T & Katzschner I	2019	Generic monitoring of European hares to determine proportion of time spent foraging in early maize in Central Europe. RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, Germany Report No. R1740045 GLP, Unpublished Syngenta File No. NA_14950	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. refers to above mentioned studies	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
						within this document	
KCP 10.1.2.2	Allen L.	2019	Mesotrione – Mesotrione – Foliage Decline Study on Clover in Hungary, Germany, United Kingdom, North-ern France and Belgium in 2018. CEMAS, Imperial House, Oaklands Park, Wokingham, Berkshire, RG41 2FD, , UK Report No. CEMR-8397 GLP, Unpublished Syngenta File No. A12738A_10535	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 10.1.2.2	Murfitt R., Fou-doulakis M., Ebeling M., Guth K., Brugger K.	2015	Measured residues on maize foliage for use in bird and mammal risk assessment' Syngenta, Bracknell, UK; and others. Poster presented at SETAC Barcelona, 2015 Not GLP published	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 10.2.	Hengsberger A., Wydra V. (report amendment 2; Kosak L., Wydra V.)	2015 (amend.2 2016)	Mesotrione wet paste (ZA1296) - Toxicity to the aquatic plant Lemna gibba in a semi-static growth inhibition test with a subsequent recovery period Syngenta Crop Protection AG, Basel, Switzerland IBACON GmbH, Rossdorf, Germany, 105732240 GLP not published Syngenta File No ZA1296_10438	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
						within this document	
KCP 10.2.	Gonsior G.	2017	Mesotrione - Growth inhibition of Myriophyllum spi-catum in a water/sediment system Syngenta Crop Protection AG, Basel, Switzerland Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S16-06273 GLP not published Syngenta File No ZA1296_10504	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 10.4.2.1	Dickinson R.	2015	R169649 - Collembola (Folsomia candida) Reproduction Test in Soil Syngenta Crop Protection AG, Basel, Switzerland AgroChemex Ltd, Manningtree, United Kingdom, ENV-14-015 GLP not published Syngenta File No CA3511_10011	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta
KCP 10.4.2.1	Ramsden C.	2015	R169649 - Predatory Mite (Hypoaspis (Geolaelaps) aculeifer) Reproduction Test in Soil Syngenta Crop Protection AG, Basel, Switzerland AgroChemex Ltd, Manningtree, United Kingdom, ENV-14-012 GLP not published Syngenta File No CA3511_10010	N	N	Callisto 100 SC is the original product to which Innvigo Sp. z o.o. would like to refer. 10 years for regis-tration data of Callisto 100 SC was expired in Poland. Thus, the data protection of studies provided in registration report of Callisto 100 SC has expired. Innvigo Sp. z o.o. re-fers to above mentioned studies within this document	Syngenta

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
KCP 2.6.1	Halarnakar R.	2012	A12739A - Chemical characterization before storage of batch SAV1K00058 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMG11364 GLP not published Syngenta File No A12732A_10001	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 2.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.5.1.2 KCP 2.8.7.2	Khot S.	2012	A12739A - Technical properties of batch SAV1K00058 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMN10807 Not GLP not published Syngenta File No A12732A_10006	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.8.3.2 KCP 2.8.5.1.1	Khot S.	2012a	A12739A - Physical properties of batch SAV1K00058 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMG11365 GLP not published Syngenta File No A12732A_10008	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 2.7.2	Kundel P.	2012	A12739A - Storage stability and shelf life statement (8	N	N	Study report have been sub-	Syngenta

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
			weeks 40 -C) in packaging made of HDPE Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Munchwilen, Switzerland, 10512883 Not GLP not published Syngenta File No A12739A_10446			mitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCP 2.8.7.2	Buser H.P.	2005	A-12739 A - Mesotrione formulation (YF11645) - Pourability data Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Not GLP not published Syngenta File No ZA1296/1855	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 2.8.7.2	Wochner F.	2007	A12739A - Gravimetric assessment of residue and rinsed residue (triple rinsing) after storage (2 years 25-C) in packaging made of HDPE Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection Munchwilen AG, Munchwilen, Switzerland, 10068880 Not GLP not published Syngenta File No ZA1296/2594	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 2.11	Kundel P.	2012a	A12739A The Effectiveness of the Spray Tank Cleaning Procedure, Final Report Syngenta Crop Protection AG, Switzerland Not GLP not published	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired because	Syngenta

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 File No 10493941			this study was used to during first review of this product or was reviewed in the EU.	
KCP 5.1.2	Alferness PL	1999	ZA1296: Liquid Chromatographic Determination with Fluorescence Detection of ZA1296 & 4-(Methylsulfonyl)-2-Nitrobenzoic Acid in Crops after Conversation to 2-Amino-4-(Methylsulfonyl)-Benzoic Acid - A Modification of TMR0643B Zeneca Agrochemicals, Jealott's Hill, United Kingdom, TMR0882B Not GLP, not published Syngenta File No ZA1296/0121	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2 KCP 5.2	Bolygo, E.	1996	ZA 1296: Independent Laboratory Confirmation of an Analytical Method for Liquid Chromatographic Determination with Fluorescence Detection of ZA 1296 and 4-(methylsulfonyl)-2-nitrobenzoic acid in Crops after Conversion to 2-amino-4-(methylsulfonyl)-benzoic acid Zeneca Report No. RJ2149B	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2	Crook S.	2002	Mesotrione: Residue Analytical Method for the Determination of Residues of Mesotrione and 4-(Methylsulfonyl)-2-Nitrobenzoic Acid (MNBA) in Crop Samples Syngenta Crop Protection AG, Basel, Switzerland Syngenta – Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RAM 366/01, 2704-01 Not GLP, not published Syngenta File No ZA1296/0752	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta

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 5.1.2	Hill S.	2004	Report revision: Mesotrione and MNBA (Metabolite) : Validation of a Residue Analytical Method (RAM 366/01) for the Determination of the Residues in Maize Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RJ3253B GLP, not published Syngenta File No ZA1296/0655	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2	Bruns G., McLean N., Nelson S.	2001	Independent Laboratory Validation of the Analytical Method, "Residue Analytical Method for the Determination of Residues of Mesotrione and 4-(Methylsulfonyl)-2-Nitrobenzoic acid (MNBA) in Crop Samples". Syngenta Crop Protection AG, Basel, Switzerland Enviro-Test Laboratories, Edmonton, Alberta, Canada, 01SYN83.REP GLP, not published Syngenta File No ZA1296/0656	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2	Watson G.	2013	Mesotrione - Validation of Syngenta Method RAM 366/01 for the Determination of Residues of Mesotrione and MNBA in Crop Matrices by LC-MS/MS Syngenta Eurofins Agroscience Services Ltd, Wilson, UK, S12-03629 GLP, not published Syngenta File No ZA1296_10101	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2	Liedtke A.	2013	SYN546974 - Toxicity to the aquatic higher plant Lemna gibba in a 7-day growth inhibition test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D77394	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this	Syngenta

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
			GLP, not published Syngenta File No SYN546974_10001			study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCP 5.1.2	Liedtke A.	2013a	R44276 - Toxicity to the Aquatic Higher Plant Lemna gibba in a 7-Day Growth Inhibition Test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D55614 GLP, not published Syngenta File No R044276_10001	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2	Liedtke A.	2013b	R169649 - Toxicity to the Aquatic Higher Plant Lemna gibba in a 7-Day Growth Inhibition Test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D55592 GLP, not published Syngenta File No CA3511_10001	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2	Volz E.	2005	Mesotrione 100 SC Formulation (A12739A): Toxicity to Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum) in a 96-hour algal growth inhibition test Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, A18325 2031806 GLP, not published Syngenta File No ZA1296/2049	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months	Syngenta

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
						have passed since the renewal of Callisto 100 SC in Poland	
KCP 5.2	Watson G., Crook S.	2013	Mesotrione - Analytical Method (GRM007.11A) for the Determination of Residues of Mesotrione and 4-(Methylsulfonyl)-2-Nitrobenzoic Acid (MNBA) in Crop Matrices by LC-MS/MS Syngenta Eurofins Agroscience Services Ltd, Wilson, UK, GRM007.11A Not GLP, not published Syngenta File No ZA1296_10102	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2	Amic S.	2013	Mesotrione - Independent Laboratory Validation of Syngenta Method GRM007.11A for the Determination of Residues of Mesotrione and MNBA in Crop Matrices by LC-MS/MS Syngenta Eurofins Agroscience Services Chem SAS, Vergèze, France, S13-02460 GLP, not published Syngenta File No ZA1296_10120	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2	Watson G.	2013a	Mesotrione - Validation of the QuEChERS Method for the Determination of Residues of mesotrione in Crop Matrices by LC-MS/MS Syngenta Eurofins Agroscience Services Ltd, Wilson, UK, S12-03251 GLP, not published Syngenta File No ZA1296_10090	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2	Zawadsky C.	2013	Mesotrione SC (A12739A) - Assessment of Toxic Effects on the duckweed Lemna gibba in a 7 day Semi-	N	N	Study report have been submitted before to Poland This	Syngenta

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
			Static Test and 14 day Recovery Period Syngenta Crop Protection AG, Basel, Switzerland Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S12-03986 GLP not published Syngenta File No A12739A_10273			study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCP 5.1.2	Chamkasem N.	2004	Analytical Method 6179-04 for the Determination of Mesotrione and its Degradates AMBA and MNBA in Water by Direct Injection High Performance Liquid Chromatography with Mass Spectrometric Detection Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T006179-04 GLP, not published Syngenta File No ZA1296/1508	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.1.2	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.2	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 Agroscience Services Chem SAS, Vergèze, France, S12-04607	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the	Syngenta

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
			GLP, not published Syngenta File No ZA1296_10129			article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCP 5.2	Jutsum L., Williams R.	2013	Mesotrione - Analytical Method GRM007.10A for the Determination of Mesotrione and its Metabolites AMBA and MNBA in Soil Syngenta CEMAS, North Ascot, United Kingdom, GRM007.10A Not GLP, not published Syngenta File No ZA1296_10092	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.2	Jutsum L., Chamkesam N.	2013	Mesotrione – Analytical Method GRM007.09A for the Determination of Mesotrione and its Metabolites AMBA and MNBA in Water Syngenta CEMAS, North Ascot, United Kingdom, GRM007.09A Not GLP, not published Syngenta File No ZA1296_10091	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.2	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	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta

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 5.2	Jutsum L.	2013b	Mesotrione - Residue Method GRM007.08B for the Determination of Mesotrione in Air Syngenta CEMAS, North Ascot, United Kingdom, GRM007.08B Not GLP, not published Syngenta File No ZA1296_10089	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 5.2	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	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 7	[redacted]	2005a	Mesotrione 100g/l SC Formulation (A12739A): Acute Dermal Toxicity Study In Rats [redacted] GLP not published [redacted]	Y	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 7	[redacted]	2005b	MESOTRIONE 100 G/L SC FORMULATION (A12739A): Primary Skin Irritation Study in Rabbits (4-Hour Semi-Occlusive Application) [redacted]	Y	N	Study report have been submitted before to Poland Data protection of this study was expired because this study	Syngenta

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
			GLP not published [redacted]			was used to first registration of Callisto 100 SC in Poland (27.02.2009r)	
KCP 7	[redacted]	2005c	Mesotrione 100g/l SC Formulation(A12739A): Primary Eye Irritation Study in Rabbits [redacted] GLP not published [redacted]	Y	N	Study report have been submitted before to Poland Data protection of this study was expired because this study was used to first registration of Callisto 100 SC in Poland (27.02.2009r)	Syngenta
KCP 7	[redacted]	2005	Dermal Sensitization Study in Guinea Pigs (Buehler Method) with Mesotrione SC (100) (A12739A) [redacted] GLP not published [redacted]	Y	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 7.3	xxxxxxxxxxx	2013	Mesotrione 100 SC (A12739A) - In Vitro Absorption through Human Dermatomed Skin using [14C-Radio-labelled]-Mesotrione xxxxxxxxxxxxxx GLP not published Syngenta File No A12739A_10438	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCA 6.1	Wiebe, L.A.	1997	ZA 1296: Stability of ZA 1296 and the Metabolite MNBA in Frozen Crops (Interim Report). Zeneca Report No:RR 97-042B INT	N	N	Study report have been submitted before to Poland. This study is available on EU	Syngenta

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
			GLP, not published			level. Data protection of this study was expired because this study was used to inclusion Mesotrione on Annex I.	
KCA 6.1	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	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCA 6.2.1	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 1287-01 GLP, not published Syngenta File No ZA1296/1350	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCA 6.2.1	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	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC)	Syngenta

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
						No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCA 6.2.1	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	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCA 6.2.1	Tarr, J.B. *et al*	1997	[Phenyl-U-14C]ZA 1296: nature of the residues in corn	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired because this study was used to inclusion Mesotrione on Annex I.	Syngenta
KCA 6.2.1	Wei, Y. *et al*	1997	[Cyclohexane-2-14C]ZA 1296: Nature of the Residues in Corn (Zea mays). Zeneca Agrochemicals Report : RR 96-026B	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired because this study was used to inclusion Mesotrione on Annex I.	Syngenta
KCA 6.3	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	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this	Syngenta

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
			GLP not published Syngenta File No ZA1296/0409			study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCA 6.3	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 Crop protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, T011085-06 GLP not published Syngenta File No A15189G_10009	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCA 6.3	Heillaut C	2009a	Glyphosate, Mesotrione and S-Metolachlor - Residue Study on GA21 (MON-00021-9) Corn in Denmark and Sweden in 2008 Syngenta Crop protection AG, Basel, Switzerland ADME - Bioanalyses, Vergeze, France, T009533-07-REG GLP not published Syngenta File No A15189G_10014	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCA 6.3	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	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023	Syngenta

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
			GLP not published Syngenta File No A14203B_10105			r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCA 6.3	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	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCA 6.3	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	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCA 6.6.1	Gorder, G.W. et al	1997	[Phenyl-U-14C]ZA 1296: confined accumulation studies on rotational crops – low rate	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired because this study was used to inclu-	Syngenta

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
						sion Mesotrione on Annex I.	
KCA 6.6.1	Spillner, C. et al	1997	[Cyclohexane-2-14C]ZA 1296: confined accumulation studies on rotational crops – low rate	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired because this study was used to inclusion Mesotrione on Annex I.	Syngenta
KCA 6.6.2	Barnes, J.P., Wiebe, L.A	1997	ZA 1296: Residue Levels on Rotated Crops from Trials Carried Out in the United States During 1995-1996. Zeneca Report No:RR 97-044B	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired because this study was used to inclusion Mesotrione on Annex I.	Syngenta
KCP 9.1.1/71	Fish L.	2013	GIS study of the proportion of acid and alkaline soils under maize crop in Europe Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ1012B Not GLP, not published Syngenta File No ZA1296_10160	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/72	Hand L.	2013	Mesotrione - Assessment of the significance of unidentified components from harsh extraction of soil residues in 14Ccyclohexanedione labelled mesotrione soil metabolism studies Syngenta	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC)	Syngenta

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 - Jealott's Hill, Bracknell, United Kingdom, Not GLP, not published Syngenta File No ZA1296_10185			No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCP 9.1.1/73	Graham R., Gilbert J.	2013	Mesotrione - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies to Derive Modelling and Persistence Endpoint DT50 Values Syngenta Battelle UK Ltd., Ongar, United Kingdom, NC/11/059C Not GLP, not published Syngenta File No ZA1296_10135	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/74	Bramley YM, Pinheiro S I, Verity A A	2002	Mesotrione Comparison of Adsorption Properties of Mesotrione and Its copper Salt in Four Soils Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel Switzerland, RJ3289B GLP, not published Syngenta File No ZA1296/0831	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/75	Hurst L.	2013	SYN546974 - Adsorption and Desorption Properties of Phenyl-U- 14C-SYN546974, a Metabolite of Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, 8252095 GLP, not published	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months	Syngenta

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
						have passed since the renewal of Callisto 100 SC in Poland	
KCP 9.1.1/76	Marth, J.L.	1997	[14C]AMBA, a Metabolite of ZA 1296: Rate of Degradation in Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-032 In DAR (1999) GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired because this study was used to inclusion Mesotrione on Annex I.	Syngenta
KCP 9.1.1/77	Miller, M.M.	1997	[Phenyl-U-14C]ZA 1296: Route and Rate of Degradation in Wisconsin Silt Loam Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-033B In DAR (1999) GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/78	Miller, M.M., Wilson, W.R.	1997	[phenyl-U-14C]ZA 1296. Rate of Degradation in Three Soils Under Aerobic Laboratory Condition. Zeneca Agrochemicals Report No: RR96-099B GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta

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 9.1.1/79	Subba-Rao, R.V.	1996	[Phenyl 14C-ZA 1296. Aerobic soil metabolism study. Zeneca Agrochemicals Report No: RR95-082B GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/80	Tarr, J.B.	1997	[phenyl-U-14C]ZA 1296. Metabolism in Thirteen Soils Under Aerobic Conditions. Zeneca Agrochemicals Report No: RR93-092B GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/81	Vispetto, A.R., Tovshtey n, M.	1996	[cyclohexane-2-14C]ZA 1296. Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR95-048B GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta

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 9.1.1/82	Vispetto, A.R., Tovshtey n, M.	1997	Addendum to: [Cyclohexane-2-14C]ZA 1296. Aerobic soil metabolism study. Zeneca Agrochemicals Report No: RR95-047B ADD GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/83	Lay, M.M	2000	[Phenyl-U-14C] AMBA : Rate of Degradation in Soil under Aerobic Laboratory Conditions Zeneca Ag products Western Research Center Report No RR 99-096B GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/84	Graham, D.G. et al	1997a	Field Soil Dissipation Study Carried Out in France During 1995-1996. Zeneca Agrochemicals Report No: RR97-026B GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta

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 9.1.1/85	Graham, D.G. et al	1997b	Field Dissipation Study Carried Out in Italy During 1995-1996. Zeneca Agrochemicals Report No: RR97-025B GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/86	Graham, D.G. et al	1997c	Field Dissipation Study Carried Out in Germany During 1995-1996. Zeneca Agrochemicals Report No: RR97-051B GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/87	Graham, D.G. et al	1998a	Field Dissipation Study Carried Out in Germany During 1996-1997. Zeneca Agrochemicals Report No: RR97-067B GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta

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 9.1.1/88	Graham, D.G. et al	1998b	Field Dissipation Study Carried Out in Italy During 1996-1997. Zeneca Agrochemicals Report No: RR97-070B GLP, not published	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.1/89	Wiebe, L.A., Yeh, S. M.	1999	ZA 1296: Stability of ZA 1296 and the metabolites MNBA and AMBA in Frozen Soil (WRC-98-158). (WINO 12775). Zeneca Agrochemicals Report No: RR98-065B	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.2/67	Carley, S.E.	1996	[phenyl-U-14C]ZA 1296 Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR96-033B In DAR (1999)	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta

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 9.1.2/68	Diaz, D.G.	1995	[14C]ZA 1296. Adsorption and Desorption Properties in Soil. Zeneca Agrochemicals Report No: RR95-070B In DAR (1999)	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.2/69	Diaz, D.G.	1996a	[14C]MNBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-008B In DAR (1999)	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta
KCP 9.1.2/71	Marth, J.L.	1997	[14C]AMBA, a Metabolite of ZA 1296: Rate of Degradation in Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-032 In DAR (1999)	N	N	Study report have been submitted before to Poland. This study is available on EU level. Data protection of this study was expired 27.02.2019 r, because according to the article 59 of Regulation (EC) No 1107/2009, 10 years have passed since the first registration of Callisto 100 SC in Poland	Syngenta

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 9.2/82	Oliver R., Edwards P.	2005	Mesotrione (ZA1296): [U-14C]-Phenyl Labelled Sterile Natural Water Photolysis Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RJ3634B 04JH012 GLP, not published	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 9.2/83	Graham R., Yeomans P.	2013	Mesotrione - Aerobic Mineralisation of 14C-Phenyl Labelled ZA1296 in Surface Water Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, 8252099 GLP, not published	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 9.2/84	Graham R., Gilbert J.	2013a	Mesotrione - Aerobic and Anaerobic Aquatic Sediment Metabolism of [Phenyl-14C]-Mesotrione Syngenta Smithers Viscient (ESG) Ltd, Harrogate, UK, Covance Laboratories Limited, Harrogate, UK, 8236956 GLP, not published	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta

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 9.2/85	Hardy I.	2013a	Mesotrione - Kinetic Modelling Analysis of Data from Water Sediment Studies to Derive Modelling and Persistence Endpoint DT50 Values Syngenta Battelle UK Ltd., Ongar, United Kingdom, NC/11/059A Not GLP, not published	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.1.2.2	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.1.2.2	[redacted]	2005	Generic field monitoring of birds and mammals on maize and beet fields in Austria [redacted] GLP not published [redacted]	Y	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	BCS (SYN access)
KCP 10.1.2.2	[redacted]	2014	Generic field study on small mammals - focal species and wood mouse (Apodemus sylvaticus) PT in maize	Y	N	Study report have been submitted before to Poland This	OXN (SYN access)

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
			fields in Germany [redacted] GLP not published [redacted]			study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCP 7.1.1	[redacted]	2005	Mesotrione 100 G/L SC Formulation (A12739A): Acute Oral Toxicity Study in the Rat (Up and Down Procedure) [redacted] GLP not published [redacted]	Y	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.2	[redacted]	2005	Mesotrione 100 g/L SC formulation (A12739A): Acute toxicity to carp (Cyprinus carpio) [redacted] GLP not published [redacted]	Y	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.2	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	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the	Syngenta

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
			not published Syngenta File No ZA1296/2042			article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCP 10.2	Volz E.	2005	Mesotrione 100 SC Formulation (A12739A): Toxicity to Pseudokirchneriella subcapitata (formerly Selenastrum 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	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.2	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 Agroscience Services EcoChem GmbH, N-Osch., Germany, S12-03986 GLP not published Syngenta File No A12739A_10273	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.3.1	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta

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 10.3.1	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.2	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.2	Volz E.	2005	Mesotrione 100 SC Formulation (A12739A): Toxicity to Pseudokirchneriella subcapitata (formerly Selenastrum 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	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.2	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	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this	Syngenta

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
			Eurofins Agroscience Services EcoChem GmbH, N-Osch., Germany, S12-03986 GLP not published Syngenta File No A12739A_10273			study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCP 10.3.1	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.3.1	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.3.1	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	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the	Syngenta

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 File No A12739A_10015			article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCP 10.3.2	Fallowfield L.	2012	Mesotrione SC (A12739A) - A rate-response 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-12-41 GLP not published Syngenta File No A12739A_10010	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.3.2	Stevens J.	2012	Mesotrione SC (A12739A) - A rate-response laboratory bioassay of the effects of fresh residues on the parasitic wasp Aphidius rhopalosiphi (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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.3.2	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC)	Syngenta

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
						No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	
KCP 10.3.2	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 Syngenta File No A12739A_10275	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.3.2	Vaughan R.	2013	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.4	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months	Syngenta

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
						have passed since the renewal of Callisto 100 SC in Poland	
KCP 10.4	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.4 /	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.3.2	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 Syngenta File No A12739A_10275	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal	Syngenta

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
						of Callisto 100 SC in Poland	
KCP 10.3.2	Vaughan R.	2013	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.5	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta
KCP 10.6	Porch J., Martin K., Krueger H.	2003	ZA1296 (Mesotrione): The toxicity effects of a 100 g/litre SC 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	N	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta

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KCP 10.6	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	N	Study report have been submitted before to Poland This study is available on EU level. Data protection of this study was expired 29.06.2023 r, because according to the article 59 of Regulation (EC) No 1107/2009, 30 months have passed since the renewal of Callisto 100 SC in Poland	Syngenta