FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: MEZOT 100 SC

Product name(s): Mezot 100 SC

Chemical active substance:

Mesotrione, 100 g/L

Central

Zonal Rapporteur Member State: POLAND

CORE ASSESSMENT

(authorization)

Applicant: Elvita Sp. z o.o.

Submission date: 28/01/2021

MS Finalisation date: 09/2023; 12/2023; 04/2024

Version history

When	What
01/2021	Submission date
09/2023	ZRMs evaluated dRR submitted by Applicant
12.2023	The final Registration Report
12.2023	ZRMS verification of the reference list
04.2024	Correction of Applicant’s address

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PART A
RISK MANAGEMENT

1 Details of the application

Applicant Name: Elvita Sp. z o.o.
Applicant Address: ~~Różewo, 78-627 Różewo~~ 87-400 GOLUB-DOBRZYŃ, ul. DWORCOWA 4

Mesotrione as active substance which was included into Annex I of Directive 91/414 (current legis-lation – regulation 540/2011) by Directive 2003/68/EC (July, 11th 2003) and renewed by Regula-tion (EU) 2017/725 of April, 24th 2017.
EFSA Journal 2016;14(3):4419 conclusion on the peer review of the pesticide risk assessment of the active substance Mesotrione are considered to provide the relevant review information or a ref-erence to where such information can be found.

Member States should take particular attention to:
- the protection of operators,
- the protection of groundwater in vulnerable regions,
- the protection of mammals, aquatic and non-target plants.

1.1 Application background

This application was submitted by the company Elvita Sp. z o.o. on January 28, 2021. The application was for approval of the product Mezot 100 SC, containing 100 g of pure Mesotrione per 1 ltr.
Mesotrione is the ISO common name for 2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione (IUPAC).
The evaluated representative uses are as an herbicide on Maize.

1.2 Letters of Access

Letter of access for technical equivalence of Mesotrione technical material.
Data protection period for active substance had already been terminated. Since 30 November 2019 applicant shall be exempted from supplying the test and study in accordance with Article 34 of Regulation (EC) No. 1107/2009.

1.3 Justification for submission of tests and studies

Submitted test and study reports are necessary for first authorization because Mezot 100 SC has an unique formulation and in the Polish market similar formulation does not exist.

1.4 Data protection claims

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

2 Details of the authorization decision

2.1 Product identity

Product code	Mezot 100 SC
Product name in MS	Mezot 100 SC
Authorization number	-
Function	Herbicide
Applicant	Elvita Sp. z o.o.
Active substance(s) (incl. content)	Mesotrione 100 g/L
Formulation type	SC – Suspension Concentrate
Packaging	0.12 L; 0.25 L; 0.50 L; 1,0 L; 5 L; 10 L; 20 L; 220 L; 1000 L HDPE
Coformulants of concern for national authorizations	No co-formulants of concern.
Restrictions related to identiy	-
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	-

2.2 Conclusion

General: The evaluation of the application for **Mezot 100 SC** resulted in the decision **to grant the authorization.**

Efficacy section: registration of Mezot 100 SC in Poland should be possible. Accepted dose is 0,75-1,5l/ha. Accepted weed in Polish label: Dose 1,5 l/ha: susceptible: weeds CAPBP, CHEAL, ECHCG, GALAP, GALPA, LAMPU, POLCO, SINAR, STEME, THLAR, VIOAR. Dose 0,75 l/ha: susceptible weeds: CHEAL, POLCO, VIOAR; moderately susceptible weeds: ECHCG, THLAR.

Mammalian toxicology section:
Classification of MEZOT 100 SC: Eye Dam.1/H318; Repr.2/H361d; STOT RE 2/H373. The operator, worker, bystander and resident (adult & child) exposure estimations carried out is acceptable.

Metabolism and residues
The evaluation of the application for Mezot 100 SC resulted in the decision to grant the authorization.

Ecotoxicology section:
Use is accepted for PL. Mezot 100 SC pose no unacceptable risk to aquatic organisms according to the label with appropriate buffer zone: 20 m no-spray buffer zone (the worst case scenario – R1 stream).
To protect non-target plants respect an unsprayed buffer zone of 5 m to non-agricultural land.

2.3 Substances of concern for national monitoring

No data.

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 Dam. 1; Repr.2; STOT RE 2**

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):	GHS05, GHS08
Signal word:	Danger
Hazard statement(s):	**H318**, **H361d, H373**
Precautionary statement(s):	**P280- Wear protective gloves/protective clothing/eye protection/face protection.** **P305 + P351 + P338** - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do continue rinsing. **P308+P313** - IF exposed or concerned: Get medical advice/attention **P314** - Get Medical advice/attention if you feel unwell. **P310** - Immediately call a POISON CENTER or doctor/physician
Additional labelling phrases:	-

** **Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of mesotrione. Adopted 14 September 2018;**
Annex VI CLP table ATP 15 (in force from 1 March 2022

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

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

-	No other phrases are required.	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).

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

-	No other phrases are required.

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:	
respective code if available	national PPE requirements
Worker protection:	
respective code if available	national PPE requirements
Integrated pest management (IPM)/sustainable use:	
respective code if available	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	
Respective code if available	According to mitigation measures (vegetated filter strip; spray drift reduction), use of Mezot 100 SC cause accepted effect to aquatic organisms: 1. Maize - 20 m no-spray buffer zone.
Other specific restrictions	
-	none

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. 1, date: 2021-01-28

PPP (product name/code):	Mezot 100 SC	Formulation type:	SC – suspension concentrate
Active substance 1:	Mesotrione	Conc. of as 1:	100 g/l
Applicant:	Elvita Sp. z o.o.	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	no		
Field of use:	Herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safen-er/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Poland	Maize	F	~~*Anthemis arvensis, Elymus repens, Amaranthus retroflexus*~~, *Capsella bursa-pastoris, Chenopodium album, Echinochloa crus-galli,* ~~*Falconeria, Fumaria officinalis,*~~ *Galium aparine, Galium palustre, Lamium purpureum,* ~~*Tripleurospermum inodorum,*~~ *Fallopia convolvulus, Sinapis arvensis,* ~~*Solanum nigrum,*~~ *Stellaria media, Thlaspi arvense, Viola arvensis.*	Foliar spraying; small drops	BBCH 12-18	1	-	a) 1,5 a) 1,5	a) Mesotrione - 150	200-300	-	Herbicide for use with field sprayers

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogenous creamy liquid of characteristic odour. It is not explosive, has no oxidising properties. The product has a self-ignition temperature of 410°C. In aqueous solution, it has a pH value around 2,97 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.

Its technical characteristics are acceptable for a *Suspension Concentrate* formulation.

The intended concentration of use is 0.5 – 0.75 % v/v

No tank mixes recommended

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling has been provided and is considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

This document summarises the information related to the efficacy of the plant protection product Mezot 100 SC. The formulation of this product is a suspension concentrate (SC) and it comprises the active substance Mesotrione (100 g/l). Mezot 100 SC is a systemic hrbicicide used for the control of the more important weeds in maize. Formulations containing Mesotrione, alone or co-formulated with other compounds are registered for use on a wide variety of crops. Registration covers use as foliar spray on maize. The active ingredient is used in maize to control weeds such as *Capsella bursa-pastoris, Chenopodium album, Echinochloa crus-galli, Galium aparine, Galium palustre, Lamium purpureum, Fallopia convolvulus, Sinapis arvensis,Stellaria media, Thlaspi arvense, Viola arvensis.*
Mezot 100 SC is used for foliar application.

3.3 Efficacy data

Preliminary studies on product Mezot 100 SC were not carried out because this herbicide contains active substance which is a well-known active substance that has been used for many years in agri-cultural practice. Preliminary studies have not been conducted because the active substance is known and has long been used in maize. The active substance of Mezot 100 SC – are registered and has been commonly used in agricultural practice for many years. The effect of the active substance is well known and sufficient large scale efficacy trials are available to evaluate the effective-ness of Mezot 100 SC. The performance of active substance is known to the authorities, and it is used as a reference standard in official efficacy trials. Therefore, preliminary tests are not described and not required.
To demonstrate the minimum effective dose rate, Mezot 100 SC was applied at 0,75 l/ha; 1,0 l/ha; 1,20 l/ha; 1,25 l/ha; 1,5 l/ha. These rates reflect 50%, 60-80% and 100% of the full recommended rate of active substances, in accordance with the EPPO guideline PP 1/225(1) “Minimum effective dose”.
The proposed dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. To fully challenge the product efficacy was tested under a range of environmental conditions.In the appropriate researches of efficacy were tested several doses and to register was chosen the lowest effective.

Summary and conclusions on the biological efficacy.

EPPO Standard PP 1/226 Number of efficacy trials provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278 Principles of zonal data production and evaluation), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

The applicant was notified that according to PP 1/226 at least 6 trials are required. **Number of trials for efficacy and selectivity from North-East EPPO zone is sufficient.** In total Applicant submitted 12 efficacy trials conducted on maize in two growing seasons: 2019 and 2020.

All details about efficacy methodology used during efficacy trials are presented above by Applicant. The reports include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards. Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized.

Data were presented correctly by Applicant in the tables. Results were comparable to standard reference product used during trials. All trials and weed species were characterized by sufficient level of infestation. Only trials with greater than 5 weeds/m^2 or over 2% ground cover have been included. For major weeds at least 4 studies should be presented and for minor- at least 2. Classification of weed species was done according to Polish requiremenets by ZRMs.

Below we present a list of studied weed species during trials:

- ***Dose 1,5 l/ha***

ANTAR – 1 trial. Due to not enough of number trials this weed species should be deleted from GAP table and label project.

AGREE– 1 trial. Due to not enough of number trials this weed species should be deleted from GAP table and label project.

AMARE – 2 trials. Due to not enough of number trials this weed species should be deleted from GAP table and label project. AMARE is a major weed in maize so at least 4 trials are required.

CAPBP – 4 trials. Number of trials is accepted. It can be concluded that CAPBP at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

CHEAL – 12 trials. Number of trials is accepted. It can be concluded that CHEAL at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

ECHCG – 11 trials. Number of trials is accepted. It can be concluded that ECHCG at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

FALCO– 1 trial. Due to not enough of number trials this weed species should be deleted from GAP table and label project.

FUMOF– 1 trial. Due to not enough of number trials this weed species should be deleted from GAP table and label project.

GALAP– 3 trials. Number of trials is accepted. It can be concluded that GALAP at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

GALPA – 4 trials. Number of trials is accepted. It can be concluded that GALPA at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

LAMPU – 3 trials. Number of trials is accepted. It can be concluded that LAMPU at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

MATIN– 1 trial. Due to not enough of number trials this weed species should be deleted from GAP table and label project.

POLCO – 5 trials. Number of trials is accepted. It can be concluded that POLCO at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

SINAR – 2 trials. Number of trials is accepted. It can be concluded that SINAR at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

SOLNI– 1 trial. Due to not enough of number trials this weed species should be deleted from GAP table and label project.

STEME – 4 trials. Number of trials is accepted. It can be concluded that STEME at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

THLAR – 7 trials. Number of trials is accepted. It can be concluded that THLAR at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

VIOAR – 6 trials. Number of trials is accepted. It can be concluded that VIOAR at recommended dose (1,5 l/ha) is a susceptible weed against MEZOT 100 SC.

In the opinion of ZRMs weed species which occurred only in 1 trial, should be excluded from label. Weeds excluded from GAP table and label project are: ANTAR, AGREE, FALCO, FUMOF, MATIN, SOLNI and AMARE.

- ***Dose 0,75 l/ha***

ANTAR – lack of trials. This weed species should be deleted from GAP table and label project.

AGREE– 1 trial. Due to not enough of number trials this weed species should be deleted from GAP table and label project.

AMARE – lack of trials. This weed species should be deleted from GAP table and label project.

CAPBP – lack of trials. This weed species should be deleted from GAP table and label project.

CHEAL – 5 trials. Number of trials is accepted. It can be concluded that CHEAL at recommended dose (0,75 l/ha) is a susceptible weed against MEZOT 100 SC.

ECHCG – 5 trials. Number of trials is accepted. It can be concluded that ECHCG at recommended dose (0,75 l/ha) is a moderately susceptible weed against MEZOT 100 SC.

FALCO– lack of trials. This weed species should be deleted from GAP table and label project.

FUMOF– lack of trials. This weed species should be deleted from GAP table and label project.

GALAP– 1 trial. Due to not enough of number trials this weed species should be deleted from GAP table and label project.

GALPA – lack of trials. This weed species should be deleted from GAP table and label project.

LAMPU – 1 trial. Due to not enough of number trials this weed species should be delet-ed from GAP table and label project.

MATIN– lack of trials. This weed species should be deleted from GAP table and label project.

POLCO – 5 trials. Number of trials is accepted. It can be concluded that POLCO at rec-ommended dose (0,75 l/ha) is a susceptible weed against MEZOT 100 SC.

SINAR – 1 trial. Due to not enough of number trials this weed species should be delet-ed from GAP table and label project.

SOLNI– lack of trials. This weed species should be deleted from GAP table and label project.

STEME – lack of trials. This weed species should be deleted from GAP table and label project.

THLAR – 2 trials. Number of trials is accepted. It can be concluded that THLAR at recommended dose (0,75 l/ha) is a moderately susceptible weed against MEZOT 100 SC.

VIOAR – 4 trials. Number of trials is accepted. It can be concluded that VIOAR at recommended dose (0,75 l/ha) is a susceptible weed against MEZOT 100 SC.

In the opinion of ZRMs weed species which occurred only in 1 trial, should be excluded from label. Weeds excluded from GAP table and label project are: ANTAR, AGREE, AMARE, CAPBP, FALCO, FUMOF, GALAP, GALPA, LAMPU, MATIN, SINAR, SOLNI, STEME.

SUMMARY: Mezot 100 SC (product code: Mezot 100 SC) is an early post-emergence herbicide (BBCH 12-18) in maize to weeds.
Crop: maize
Growth stage of the crop: BBCH 12-18

Product dose rate: 1,5 l/ha 1x per crop
Water: 200-300 L/ha

Accepted weed in Polish label:

Dose 1,5 l/ha:

-*susceptible*: weeds CAPBP, CHEAL, ECHCG, GALAP, GALPA, LAMPU, POLCO, SINAR, STEME, THLAR, VIOAR.

Dose 0,75 l/ha:

susceptible weeds: CHEAL, POLCO, VIOAR
moderately susceptible weeds: ECHCG, THLAR

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

Resistance is the naturally inherited ability of some weed biotypes within a popułation to survive an application of herbicides, which would control this weed population on normal application conditions effectively. Resistance is of great commercial relevance both for the operator and for the manufacturer. For the operator due to the fact that less efficacy represent yield losses of qualitative and quantitative nature and resulted in higher costs of weed con-trol: for the manufacturer because development of resistance could ruin the return of investment in the develop-ment of an active substance.
The active substance is a competitive inhibitor of 4-hydroxyphenyl pyruvate dioxygenase (HPPD) in the plastoquinone biosynthesis pathway, which in turn disrupts carotenoid biosynthesis and leads to a disruption of chlorophyll synthesis. In susceptible species bleaching and death occurs.
The compound is classified by the Herbicide Action Committee in HRAC group F2.
According to the International Survey on Herbicide Resistant Weeds [www.weedscience.org], there are just two species that show resistance to mesotrione, world-wide (six reported cases); Amaranthus palmeri and Amaranthus tuberculatus (A. rudis). Both resistant species have occurred in maize 'corn' grown on continuous/extended rotations or where grown as seed crops (where alternative products are limited). The mechanism(s) of resistance for these biotypes is unknown and as yet unclassified. There are currently no reports of weed species resistant to mesotrione within the EU or Europe.

Mesotrione have been used as straight products as well as in mixtures for many years. Without any precautions, the resistance risk is unacceptable. However, taking the right precautions and following Good Agricultural Practise, the risk is acceptable. Should resistant populations arise, control could be achieved through use of alternative products.

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

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

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

3.3.2 Phytotoxicity to host crop

In all trials conducted phytotoxicity was assessed. Phytotoxicity assessment of the tested product (Mezot 100 SC) was made in 8 trials. No case of significant adverse effects were recorded on any cultivars at the proposed dose rates of 1,5 L/ha.
No signs of phytotoxicity effects were observed in all trial. Phytotoxicity in tested samples was 0%.
No phytotoxicity for Mezot 100 SC and the reference standards was observed throughout the trials.
At any tested rate, Mezot 100 SC was perfectly safe for all crops and cultivars tested in the efficacy programme.

3.3.3 Observations on other undesirable or unintended side-effects

For a preliminary estimate of the impact on succeeding crops, a laboratory study on seedling emergence may by indicated. Positive assessment and details are described in dRR Section 9 this registration documentation.
Additionally it is concluded that after the appropriate application of Mezot 100 SC in cereals, all the possible following crops can be grown in the frame of usual crop rotation without ploughing. In case it is necessary to close down the plantation where the product was used (as a result of crop damage caused by frost, disease or pest), it is possible to grow maize.
None of the efficacy trials reported any effects on adjacent crops or plants. Application of Mezot 100 SC according to the requirements of "Good Agricultural Practice" excludes lapses e.g. overspray of boundary stripes, overdose or applications in other than the registered crops or at other application times. Furthermore, Good Agricultural Practice avoids spray drift to adjacent crops by taking into account the wind speed, the droplet size and positioning of the spray boom. As Mezot 100 SC is intended for control of dicotyledonous weeds, the product may cause damages on dicotyledonous adjacent crops if it is misused.
During the course of the effectiveness trials observations indicating any effects whatsoever on beneficial or other non-target organisms were not reported. Furthermore, the lack of observations of negative impacts on non-target organisms is in accordance with the results of toxicity tests in ecotoxicologically relevant indicator species. Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).
Summary and conclusion:
Mezot 100 SC is a herbicide without any unexpected action and to be harmful for any succeeding crop. There are no important phytotoxic effects on treated or on succeeding crops. There are no important phytotoxic effects on treated or on succeeding crops. Use of Mezot 100 SC in accordance with the proposed scope of use (GAP) and the Principles of Good Agricultural Practice does not pose a risk to neighboring plants. During the course of the effec-tiveness trials observations indicating any effects whatsoever on beneficial or other non-target organisms were not reported.

3.4 Methods of analysis (Part B, Section 5)

Presented methods for determination of Mesotrione and relevant impurities in the product Mezot 100 SC are specific. The validation parameters are within the acceptance range and fulfil EU requirements given in SANCO /3030 /99 rev. 5. See dRR Part B5 for details.

3.4.1 Analytical method for the formulation

With respect to toxicological, eco-toxicological or environmental aspects Mezot 100 SC does not contain any relevant formulants. Therefore, a special analytical method and validation is not needed.

3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.
Noticed data gaps are:
- none

Commodity/crop	Supported/ Not supported
Maize	Supported

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

Summary of evaluation of the studies on acute toxicity for product Mezot 100 SC

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (OECD 423)	Not submitted, not necessary. Justification presented in Appendix 2			
LD_{50} dermal, rat	Not submitted, not necessary. Justification presented in Appendix 2			
LC_{50} inhalation, rat	Not submitted, not necessary. Justification presented in Appendix 2			
Skin corrosion, in vitro (OECD 431)	Non-corrosive	yes	None	[redacted] 2019
Skin irritation, in vitro (OECD 439)	Not submitted, not necessary.			
Eye irritation/damage, in vitro (OECD 438)	Not eye damage	yes	None	[redacted] 2019
Eye irritation/corrosion, in vivo (OECD 405)	Eye Damage.	yes	**H318/Eye Dam.1**	[redacted] 2020
Skin sensitisation, guinea pig	Not submitted, not necessary. Justification presented in Appendix 2			
Supplementary studies for combinations of plant protection products	No data – not required	yes		

Aditionally Repr.2/H361d; STOT RE 2/**H373 according Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of mesotrione. Adopted 14 September 2018;** Annex VI CLP table ATP 15 (in force from 1 March 2022

Additional toxicological information relevant for classification/labelling of Mezot 100 SC.

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	Mesotrione (9,23 % (w/w))	Aquatic Acute 1; H400 Aquatic Chronic 1; H410	Reg. 1272/2008	Relevant Aquatic Chronic 1; H410
Toxicological properties of non-active substance(s) (relevant for classification of product)	Etoxylated iso C 9-11, C10 alcohol; CAS: 78330-20-8 (0,92 % (w/w))		MSDS	Not relevant
	1,2-benzisothiazolin-3-one; CAS: 2634-33-5 (< 0,001 % (w/w)	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Skin Sens. 1; H317 Aquatic Acute 1; H400	MSDS	Not relevant
	Sodium hydroxide;	Skin Corr. 1A; H314	MSDS	Not relevant

	Substance (Concentration in product, % w/w)	**Classification of the substance (acc. to the criteria in Reg. 1272/2008)**	**Reference**	**Classification of product (acc. to the criteria in Reg. 1272/2008)**
	CAS: 1310-73-2 (< 0,001 % (w/w)			
	1,2-Ethanediol; CAS: 107-21-1 (1,85 % (w/w))	Acute Tox. 4; H302	Reg. 1272/2008	Not relevant
Further toxicological information	No data – not required			

3.5.2 Operator exposure

Exposure models for intended uses

Critical uses	Maize (max. 1.5 L product/ha)
Model	AOEM Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

The operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses (gloves, protective clothing)(mixing/loading/application)
Implication for labelling: P280- Wear protective gloves/protective clothing

3.5.3 Worker exposure

Exposure models for intended uses

Critical uses	Maize (max. 1.5 L product/ha)
Model	AOEM Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Estimated worker exposure

The worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering suitable PPE

3.5.4 Bystander and resident exposure

Exposure models for intended uses

Critical uses	Maize (max. 1.5 L product/ha)
Model	AOEM Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Estimated bystander and resident exposure – model AOEM

The bystander and/or resident exposure estimations carried out according BREAM Model indicated that the acceptable operator exposure level (AOEL) for Mesotrione will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures.

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

3.6.1 Residues

Storage stability

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

Mesotrione is considered to be stable under freezer storage at -18ºC±5ºC for at least 42 months in maize grain and 31 months in maize forage. Frozen storage stability at -18ºC±5ºC of MNBA in maize grain and forage was demonstrated for at least 42 months.

Metabolism in plants and animals

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

Plant residue definition for monitoring Mesotrione (cereals and pulses/oilseeds only) - EFSA journal 2016;14(3):4419, Reg. (EU) 2017/626

Plant residue definition for risk assessment:

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

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

Magnitude of residues in plants

Proposed GAP for maize is within the EU GAP (SANTE/11654/2016, 23 March 2017).

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

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

Magnitude of residues in livestock

No new data were submitted in the framework of this application and no required. Dietary burden calculations made by the Applicant are accepted.

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

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

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

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

EFSA: we agree with the RMS conclusion that the micronucleus test gave sufficient evidence of lack of

genotoxic (clastogenic and aneugenic) potential of the metabolite AMBA since bone marrow exposure was demonstrated after 2 dosing with the substance with 24 h interval and measurement of AMBA in whole blood. We agree with the RMS that the confirmatory data requirement (1) has been fulfilled. It is however noted that the data gap identified in the EFSA conclusion (EFSA, 2016) regarding the relative toxicity of the metabolite compared with mesotrione has not been addressed.

Magnitude of residues in processed commodities

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

Magnitude of residues in representative succeeding crops

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

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

Other / special studies

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

3.6.2 Consumer exposure

Estimation of exposure through diet and other means

Chronic consumer risk assessment was performed by zRMS with EFSA PRIMo model rev. 3.1 for all commodities; the current MRLs for mesotrione (Regulation (EU) 2017/626), were used as input values.

For acute risk assessment only the crop of interest was used for the assessment.

The proposed uses of mesotrione in the formulation Mezot 100 SC do not represent unacceptable acute and chronic risks for the consumer.

TMDI (% ADI) according to EFSA PRIMo rev 3	12% NL toddler (highest contributor to MS diet: 6 % Milk, Cattle)
IEDI (% ADI) according to EFSA PRIMo rev.3	n.r.
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities: 0.3% Maize/corn (children) Unprocessed commodities: 0.1% Maize/corn (adults) Processed commodities: 1% Maize/oil (children) Processed commodities: 0.6% Maize/oil (adults)
NTMDI (% ADI) **	n.r.
NEDI (% ADI)**	n.r.
NESTI (% ARfD) **	n.r.

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

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

The PECs of Mesotrione in soil has been assessed assuming that Mesotrione is evenly distributed in the top 5 cm soil horizon with a soil bulk density 1.5 g/cm^3 and with the focus groundwater interception 25%.

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
Mesotrione	150	0,150	0,127	5	-	0,150
Mezot 100 SC	1084	1,63	-	5	-	1,63
Density of formulation – Mezot 100 SC = 1,084 g/ml (dRR Secion 1)						

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

There's no data from studies for Mezot 100 SC. Calculation was executed on basis of EU agreed end-points for Mesotrione.
The PEC_{GW} (Predicted Environmental Concentrations in Ground Water) of Mesotrione and its soil metabolites were calculated using the simulation models FOCUS-PELMO (version 5.5.3) and FOCUS-PEARL (version 4.4.4).
The results show that groundwater PEC values for the parent and metabolites are below the trigger value of 0.1 μg/L in most scenarios.

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

The EU agreed endpoints (EFSA 2010) were used.
Models used for calculation: STEPS1-2 ver.3.2
FOCUS SWASH 5.3, SPIN 2.2, FOCUS PRZM 4.3.1,
FOCUS MACRO 5.5.4, FOCUS TOXWA 5.5.3
SWAN 5.0

PEC_{sw} (μg/L)	Scenario	STEP 4	
Nozzle reduction	Vegetative strip (m)	-	-
	No spray buffer (m)	10	20
0 %	D3 ditch	0,1368	0,0712
0 %	R1 stream	1,013	0,5171
RAC (μg/L) = 0,77		**PEC/RAC ratio**	
0 %	D3 ditch	0,18	0,09
0 %	R1 stream	**1,32**	0,67

Environmental concentrations in surface water is acceptable under condition that risk mitigation measure will be used.

3.7.3 Predicted environmental concentrations in air (PEC_{air})

Compound	Mesotrione
Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT_{50} of 17.635 hours (1.5 days) derived by the Atkinson model (AOP version 1.8). OH (12h) concentration assumed = 1.5×10^6 OH/cm^3
Volatilisation	from plant and soil surfaces (BBA guideline): <10% after 24 hours
Metabolites	None

The vapour pressure at 20 °C of Mesotrione is < 10-5 Pa. Hence the active substance is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance due to volatilization with subsequent deposition should not be considered.
PECa is assumed to be negligible.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

An estimation of risk indicate low risk for birds and mammals of each range of assessed issues.
Risk assessments for Mezot 100 SC carried out according to EFSA 2009 with the proposed use pattern were provided and are considered adequate.

Birds

The acute, short and long-term risk to birds from Mezot 100 SC were assessed. TERs at Tier I showed an acceptable risk to the indicator species for each crop scenario.
Therefore, an acceptable risk to avian populations is expected from the application of Mezot 100 SC according to the recommended use pattern.

Terrestrial vertebrates (other than birds)

In the screening step the TER_A values for mesotrione exceeds the trigger value set by Commission regulation (EU) 546/2011 for acceptability of effects. Further refinement for acute risk assessment is not required. Acute risk assessment was accepted by zRMS. For metabolites – MNBA and AMBA the TER_{LT} values from the tier 1 reproductive risk assessment are above the trigger for all scenarios. Refinement risk assessment is not required. For mesotrione the TER_{LT} values from the tier 1 reproductive risk assessment are below the trigger for all scenarios. Refinement risk assessment is required.

Additional higher tier risk assessment.

The applicant of dossier for active substance Mesotrione provided a detailed refined long-term risk assessment for mammals and a range of studies for identification of focal species and PT values. The results of 3 monitoring studies indicate that the omnivorous wood mouse (*Apodemus sylvaticus*) and the herbivorous European brown hare (*Lepus europaeus*) are appropriate focal species for maize at the early stages after germination. From the results of 2 monitoring studies a maximum PT of 0.139 has been taken for the omnivorous wood mouse in early maize for use in risk assessment. No reliable quantitative estimate of the DT50 for mesotrione on maize could be determined from the residue decline study, therefore the de-

fault value of 10 days has been considered in the risk assessment. Please refer to Conclusion on the peer review of the pesticide risk assessment of the active sub-stance Mesotrione (EFSA Journal 2016;14(3):4419).

Refinement of PT value and focal species
zRMS comment: The PT value of 0.139 for wood mouse was accepted at the EU level during mesotrione evaluation. The focal species for maize at early BBCH growth stages such as wood mouse and brown hare were accepted by zRMS.

For Mezot 100 SC additional field studies of residue decline were performed. The target was to check if in fact the DT_{50} for Mesotrione on maize should be determined as much lower than 10 and real long-term risk for mammals can be acceptable.

Title	Residues of Mesotrione on maize plants after spray application of Mesotrione 100 SC in early growth stages of maize in Poland – magnitude of residues and time course of residue decline – 2019
Study code	19SGS10
Study director	Karol Łukaszewski
Study complection date	20.11.2019
Quality	The study has been conducted in compliance with the Principles of Good Laboratory Practices (GLP) as stated in: - Journal of Laws of the Republic of Poland of 24 March 2011 Act of 25 February 2011 on the Chemical Substances and Their Mixtures, - Regulation of the Minister of Health of 22 May 2013 on Good Laboratory Practice and testing in compliance with the principles of Good Laboratory Practice, - The OECD Principles of Good Laboratory Practice, as revised in 1997 [ENV/MC/CHEM (98) 17], - The application of the GLP Principles to field studies, as revised in 1999 [ENV/JM/MONO (99) 22], - The application of the OECD Principles of GLP to the Organisation and Management of Multi-site Studies, 2002 [ENV/JM/MONO (2002) 9].

Introduction:
Mesotrione is an effective herbicide for use in maize. The trial sites chosen are representative production areas of maize in Poland.

Objectives of the study:
The objective of the study was to verify residues of Mesotrione on maize plants after spray application of Mesotrione 100 SC in early growth stages of maize in Poland – magnitude of residues and time course of residue decline.

Material and methods:
Test item:

Formulation Name:	Mesotrione 100 SC
Main uses:	Herbicide
Formulation type:	Suspension concentrate - SC
Nominal Concentration:	100 g a.s./L
Batch Number:	01/19
Manufacture date:	03.2019

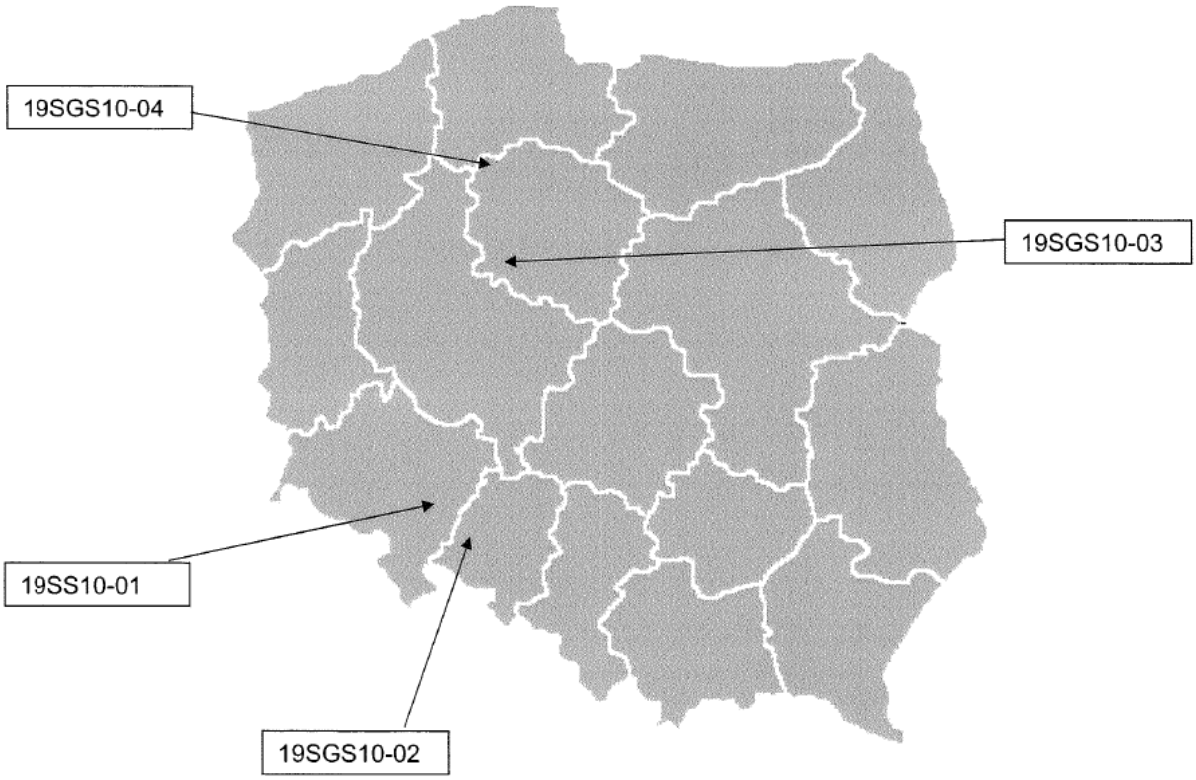
Test system:

Crop	**Maize** (*Zea mays*)
Crop Group classification	*Codex alimentarius*: GC 0645
RACs harvested	Whole plants

Trial sites and experimental design:
Four decline trials (DCS) were established in 4 different locations, in PL. Each trial consisted of 3 treated plots T1, T2, T3.
The sites were representative, grown in a way typical of the producing.
Each trial consisted of 3 treated plots T1, T2, T3. Plots were at least 1000 m^2. Untreated samples were collected before application.
Around the treated plots, a buffer zones (zone where no forbidden products are applied) were set up.
The Study Director or Principal Field Investigator provided information on soil type (texture classification). Information was obtained from certificates of analysis.
Environmental conditions did not alter the normal growth, development and maturity of the crop at the trial sites to such a degree as to have negatively impacted the integrity and validity of this study.
One typical herbicide application of Mezot 100 SC was performed in each trial with tractor sprayer on the treated plots at the target dose rate of 1,5 L/ha (equivalent to 150 g a.s./ha).
The target spray volume was 400 litres per hectare according to Good Agricultural Practices. No adjuvant was added to the spray mixture.
The application equipment consisted of commercial tractor sprayer.
Applications were performed at 12-13 BBCH crop stage.
Quality control measures were taken to maintain specimen integrity and to avoid contamination at the trial sites.
Maize was cultivated according to normal local agronomic practices. All cultivation operations, irrigation and fertilisation (when relevant) were recorded in the Field Trial Notebooks.
The trial sites received applications of maintenance pesticides but were not treated with any pesticides that interfere with the analytical method during the course of this study phase.
Crop and pesticide use history for 3 years prior to test item applications were provided by farmer and were recorded in the raw data for 2016, 2017, 2018, 2019 (current season). Only sites which have not been treated in 2016, 2017, 2018 and current season with any product containing mesotrione were selected.
Daily weather data was collected from permanent weather recording stations.
Maximum and minimum air temperature data for the trial site in this study are summarised in Field Trial Notebooks.
All specimens remained deep frozen during storage at the test sites, during shipment to the analytical laboratory SGS Polska Sp. z o.o. Environmental Laboratory and during storage at the analytical laboratory.

Identification of the field trials:

Trial number	Study type	Zone	Country (region)	Trial site	Zip code
19SGS10-01	DCS	Central Europe	Poland (dolnośląskie)	Piszkorzówek	55-216
19SGS10-02	DCS	Central Europe	Poland (opolskie)	Grodków	49-200
19SGS10-03	DCS	Central Europe	Poland (kujawsko-pomorskie)	Białożewin	88-400
19SGS10-04	DCS	Central Europe	Poland (kujawsko-pomorskie)	Jerzmionki	89-430



Test system information:

Trial number	Crop	Variety	Planting date/year	Row spacing (cm)	Plant spacing (cm)	Crop density (plants/ha)	Crop BBCH at application
19SGS10-01	Maize	Figaro	26.04.2019	75	16	82000	12-13
19SGS10-02	Maize	Topaz	01.06.2019	75	16,5	80000	12-13
19SGS10-03	Maize	MAS 17.G	19.04.2019	75	16	80000	12-13
19SGS10-04	Maize	SEIDDI CS	10.05.2019	75	16	80000	12-13

Trial data and information:

Location	Piskorzówek	Grodków	Białożewin	Jerzmionki
GPS	(N $50^0$54’14”; E $17^0$8’51,4”)	(N $50^0$41’3,5”; E $17^0$21’5,4”)	(N $52^0$50’12,88”; E $17^0$48’35,86”)	(N $53^0$36’17,12”; E $17^0$31’7,31”)
Country	Poland	Poland	Poland	Poland
Plot size (m^2)	3 x 1012,5	3 x 1012,5	3 x 1000,0	3 x 1005,0
Type of soil	Sand – 19 % Silt – 61 % Clay – 20 %	Sand – 24 % Silt – 65 % Clay – 11 %	Sand – 73 % Silt – 24 % Clay – 5 %	Sand – 77 % Silt – 21 % Clay – 2 %
pH value of soil	7,3 (water)	6,8 (KCl)	7,5 (KCl)	6,4 (KCl)
Organic Matter	3,1 %	1,9 %	1,7 %	3,6 %
BBCH crop	12-13	12-13	12-13	12-13
Seed rate (Seeds/ha)	82000	80000	80000	80000

Date of sowing	26.04.2019	01.06.2019	19.04.2019	10.05.2019
Date od application	31.05.2019	13.06.2019	27.05.2019	30.05.2019
Temp. [^{0}C]	23,6	24,9	22,5	16,0
Rainfall (mm)	500-600	400-500	300-400	400-500
Humidity [%]	80	50	46	45
Cloud cover (%)	10	50	40	10
Test itam rate (L/ha)	1,5 l/ha	1,5 l/ha	1,5 l/ha	1,5 l/ha
Water rate (L/ha)	400	400	400	400

Sumary of analytical phase:

Study Number: 19SGS10; Analytical Phase Code: DPL/122/2019

ANALYTICAL METHOD:
Specimen extraction and determination of residues of mesotrione were performed according to the multi-residue QuEChERS method.
Quantification was performed by use of LC-MS/MS detection. The limit of quantification (LOQ) of the analytical method was 0.010 mg/kg.
The extracts were analyzed using liquid chromatography coupled with mass spectrometry, by single extraction and single injection to the detection system. Final extracts were employed for LC-MS/MS analysis directly after completion of the extraction procedure (on the same day). Data acquisition was carried out in the MRM mode. The analysis was performed using internal standard addition.

For each analyte, one mass transition was evaluated and used for quantification. Representative chromatograms are shown in this report. A second mass transition was monitored for confirmation of peak identity but was not used for quantification.
Instrument settings:
Liquid Chromatograph LCMS-8050 Shimadzu consists of:
Degazer DGU-20AXR
Two pumps LC-20ADXR (Nexera)
Autosampler SIL-20ACXR
Column oven CTO-20AC
Compressor, generator PEAK Genius 1051
HPLC Column – Agilent Poroshell 120 EC-C18, 4.6 x 50 mm

For each trial DT50 value was determined. For this purpose CAKE (Computer Assisted Kinetic Evaluation, version 3.3) program, following single first-order kinetics (SFO) was used.

METHOD VALIDATION:
The method for determination of mesotrine in maize (plants) was validated at Test Facility SGS Polska Sp. z o.o., ul. Cieszyńska 52A, Pszczyna, according to SANCO/3029/99, rev. 4 guidelines and SANCO/825/00 rev. 8.1., 16/11/2010 guidelines. Validation criteria and results are summarized in table as below:

Parameter	**Criterion of acceptance**	**Obtained results**	
		338.00>290.85	338.00>211.95
Specificity/selectivity	fulfilled		
Linearity	$R^2 \geq 0.99$	$R^2 = 0.9996$	$R^2 = 0.9995$
Limit of quantification (LOQ)	-	0.010 mg/kg	

Limit of detection (LOD)	-	0.003 mg/kg	
Precision	RSD ≤ 20%	2.80% (level 0.010 mg/kg) 1.53% (level 0.10 mg/kg)	4.92% (level 0.010 mg/kg) 3.54% (level 0.10 mg/kg)
Accuracy (recovery)	70 – 120%	100.1% (level 0.010 mg/kg) 103.6% (level 0.10 mg/kg)	98.4% (level 0.010 mg/kg) 99.1% (level 0.10 mg/kg)

The method was validated according to SANCO/3029/99, rev. 4 guidelines and SANCO/825/00 rev. 8.1., 16/11/2010 guidelines.
The results acquired during validation of the analytical method (accuracy and repeatability) were in the range of 70 – 120% and RSD ≤ 20% for average recovery.
The limit of quantification of the method was established at 0.010 mg/kg for maize (plants).

There were no interfering signals at retention time of analyzed compound in examined control matrix.

The analytical method for determining the residues of mesotrione in maize (plants) meets the criteria of SANCO/3029/99, rev. 4 guidelines and SANCO/825/00 rev. 8.1., 16/11/2010 guidelines in terms of precision, accuracy and uncertainty.

Conclusions:
This study was fully performed as anticipated, in accordance with the study plan and the amendments issued. The collected specimens were suitable for the purpose of the study and the residue values can therefore be considered as representative of the crop and of the application timing(s) and rate(s).

No residues of mesotrione were detected at or above the limit of detection (LOD, 0.003 mg/kg) or limit of quantification (LOQ, 0.01 mg/kg) in any of the untreated maize samples (plants).
The residues of mesotrione in the treated maize seedlings samples taken from all trials at 1 hour after application (HAA) were in the range 5.45 to 23.22 mg/kg, at 3 HAA were in the range 5.89 to 16.73 mg/kg, at 6 HAA were in the range 5.65 to 16.69 mg/kg, at 9 HAA were in the range 2.64 to 11.93 mg/kg, at 12 HAA were in the range 1.51 to 10.61 mg/kg, at 24 HAA were in the range 1.11 to 7.12 mg/kg, at 2 days after application (2 DAA – 48 HAA) were in the range 0.17 to 2.29 mg/kg and at 3 DAA (72 HAA) were in the range 0.053 to 0.69 mg/kg. The maize seedlings samplings at 4 DAA (96 HAA) were performed for contingency purposes; these samples were not analyzed.
For each trial DT_{50} value was determined. For this purpose CAKE (Computer Assisted Kinetic Evaluation) program, following single first-order kinetics (SFO) was used. Residue decay is described by:

$$c = c_0 e^{-kt}$$

with:
c – *concentration at time t*
c_0 – *initial concentration*
k – *rate constant*
t – *time*

Determined values of DT_{50}

Trial	DT_{50} [h]	DT_{50} [days]	Error [%]
I	21.6	0.90	6.97
II	6.28	0.26	17.9
III	7.55	0.31	15.3
IV	18.4	0.77	10.7

The results of the trials show the rate of degradation of mesotrione is rapid, with a DT_{50} value in the range 0.26 days (6.28 hours) to 0.90 days (21.6 hours).

The objective of the study was the determination of residues and time course levels of mesotrione in maize specimens (plants) in four decline curve trials following one application of the formulated product Mezot 100 SC under cultural practice typical for maize production. Based on regular sampling of the maize seedlings following application the residue concentrations measured were shown to rapidly decline. DT_{50} value was calculated to be in the range 0.26 days (6.28 hours) to 0.90 days (21.6 hours).

Calculation of f_{TWA} :

$$f_{twa} = \frac{1 - e^{-kt}}{kt}$$

where k = ln2/DT50.

DT_{50} = 0,56 dni (arithmetic mean)

f_{TWA} = 0,038

DDD = rate [kg/ha] * SVm * MAF * fTWA * PT
TER = NOEL/DDD

Report title:	Supplementing kinetics with statistical evaluation to study: Residues of Mesotrione on maize plants after spray application of Mezot 100 SC in early growth stages of maize in Poland – magnitude of residues and time course of residue decline – 2019.
Sudy number:	19SGS10
Study Director:	Karol Łukaszewski

1. TRIAL 19SGS10-01

Table 1.1. Value, Predicted Value and Residual

Time (hours)	Value (mg/kg)	SFO		DFOP		FOMC	
		Predicted Value	Residual	Predicted Value	Residual	Predicted Value	Residual
1	12.67	12.26	0.4072	12.26	0.4072	12.27	0.404
3	10.52	11.5	-0.9804	11.5	-0.9804	11.5	-0.9817
6	9.86	10.45	-0.5848	10.45	-0.5848	10.44	-0.5839
9	9.97	9.486	0.4839	9.486	0.4839	9.484	0.4863
12	9.38	8.615	0.7647	8.615	0.7647	8.612	0.7679
24	6.52	5.862	0.6584	5.862	0.6584	5.858	0.6615
48	2.05	2.713	-0.6633	2.713	-0.6633	2.716	-0.6657
72	0.58	1.256	-0.676	1.256	-0.676	1.262	-0.6817

Table 1.2. Estimated Values - model SFO, DFOP, FOMC

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
SFO $C_t = C_0 e^{-kt}$							
C_0	12.66	0.5323	N/A	11.63	13.7	11.36	13.97
k	0.03209	0.003941	<0,0001	0.02444	0.03975	0.02245	0.042
DFOP $C_t = C_0 g e^{-k_1 t} + C_0(1 - g)e^{-k_2 t}$							
C_0	12.66	0.6346	N/A	11.31	14.02	10.9	14.43
k_1	0.03209	0.004384	0.0009	0.02275	0.04144	0.01992	0.044
k_2	0.03209	0.004512	0.0010	0.02247	0.04171	0.01957	0.045
g	0.5104	nd	N/A	nd	nd	nd	nd
FOMC $C_t = C_0 / [(t/\beta) + 1]^{\alpha}$							
C_0	12.83	0.5832	N/A	11.66	14.01	11.34	14.33
α	276.7	30.17	N/A	215.9	337.5	199.1	354.2
β	8.11E+003	nd	N/A	nd	nd	nd	nd

Table 1.3. Goodness of Fit

		SFO	DFOP	FOMC
Chi^2	Error %	6.97	8.03	7.45
	df	6	4	5
Decay Times	DT50 (hours)	21.6	21.6	20.3
	DT90 (hours)	71.8	71.8	67.8
Goodness of fit	R^2 (Obs v Pred)	0.9737	0.9737	0.9736
	Efficiency	0.9720	0.9720	0.9719
	r	0.9868	0.9868	0.9867
	Relative mean squared error	0.0480	0.0480	0.0484
	Relative average deviation	0.1512	0.1512	0.1515
	MAE	0.6533	0.6533	0,6530
	MPE [%]	-17.2318	-17.2318	-17.3624
	MAPE [%]	23.8163	23.8163	23.9556
	MSE	0.4532	0.4532	0.4537
	RMSE	0.6732	0.6732	0.6736
	AIC	-2.3314	1.6686	-0.3222
	BIC	-2.1725	1.9864	-0.0839

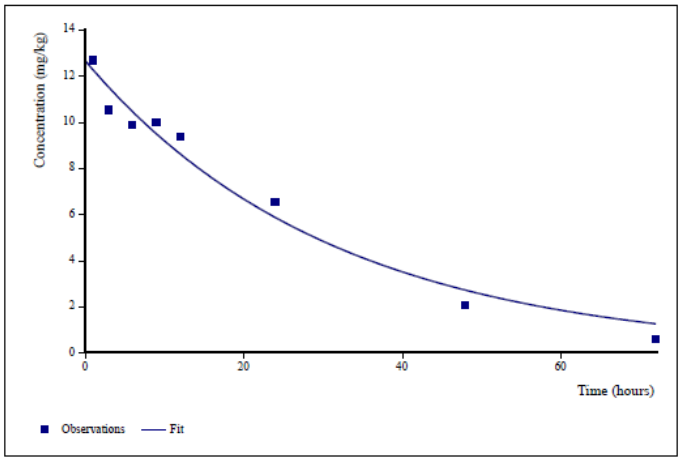


Figure 1.1. Observations and Fitted Model: SFO

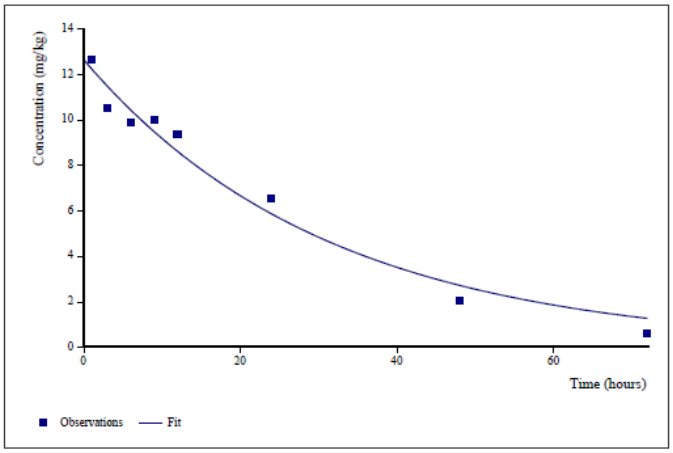


Figure 1.5. Observations and Fitted Model: DFOP

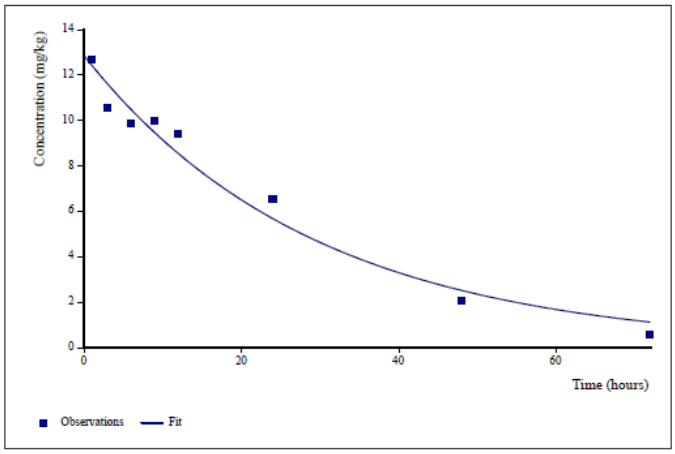


Figure 1.9. Observations and Fitted Model: FOMC

Conclusion: All 3 models have Ch^2 error below 15% and the lowest result was found for the SFO model, i.e. $Ch^{\wedge 2}$ error is 6.97%. All 3 models have a similar goodness of fit to the data with a high coefficient of determination and a similar error rate, so the complexity issues will determine the choice of model. According to the information criteria, the lowest scores also apply to the SFO model. The parameter k of this model is highly significant ($p<0.01$) and the 95% confidence interval ranges from 0.0224 to 0.0420. For the SFO model, the estimated value of DT_{50}=21.6 hours and DT_{90}=71.8 hours.
zRMS comment: Accepted.

2 TRIAL 19SGS10-02

Table 2.1. Value, Predicted Value and Residual

Time (hours)	Value (mg/kg)	SFO		DFOP		FOMC	
		Predicted Value	Residual	Predicted Value	Residual	Predicted Value	Residual
1	8.36	9.123	-0.7633	9.156	-0.7963	9.124	-0.7636
3	8.06	7.316	0.7436	7.3	0.76	7.316	0.7443
6	6.64	5.254	1.386	5.215	1.425	5.254	1.386
9	2.85	3.773	-0.9235	3.748	-0.8976	3.774	-0.9235
12	1.72	2.71	-0.99	2.714	-0.9941	2.711	-0.9909
24	1.25	0.7209	0.5291	0.8593	0.3907	0.7234	0.5266
48	0.6	0.05101	0.549	0.2913	0.3087	0.05197	0.548
72	0.061	0.003609	0.05739	0.257	-0.196	0.003777	0.05722

Table 2.2. Estimeted Values model SFO, DFOP, FOMC

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
SFO $C_t = C_0 e^{-kt}$							
C_0	10.19	1.046	N/A	8.155	12.22	7.628	12.75
k	0.1104	0.02197	0.001198	0.06767	0.153	0.0566	0.164
DFOP $C_t = C_0 g e^{-k_1 t} + C_0(1-g)e^{-k_2 t}$							
C_0	10.26	1.406	N/A	7.263	13.26	6.356	14.17
k_1	0.1169	0.06475	0.07261	-0.0211	0.255	-0.06283	0.297
k_2	1.63E-007	0.195	0.5	-0.4156	0.4156	-0.5413	0.541
g	0.9752	0.2819	N/A	0.3742	1.576	0.1925	1.758
FOMC $C_t = C_0 / [(t/\beta) + 1]^{\alpha}$							
C_0	10.67	1.173	N/A	8.311	13.04	7.659	13.69
α	667.7	nd	N/A	nd	nd	nd	nd
β	5.35E+003	nd	N/A	nd	nd	nd	nd

Table 2.3. Goodness of Fit

		SFO	DFOP	FOMC
Chi^2	Error %	17.9	20.3	19
	df	6	4	5
Decay Times	DT50 (hours)	6.28	6.15	5.55
	DT90 (hours)	20.9	21.9	18.5
Goodness of fit	R^2 (Obs v Pred)	0.9351	0.9358	0.9351
	Efficiency	0.934	0.9358	0.9339
	r	0.9670	0.9673	0.9670
	Relative mean squared error	46.1910	0.2745	42.6930
	Relative average deviation	3.5572	0.4184	3.4354
	MAE	0.7427	0.7211	0.7426
	MPE [%]	19.8679	-38.3170	19.7753
	MAPE [%]	44.6356	66.7161	44.5694
	MSE	0.6842	0.6653	0.6844
	RMSE	0.8271	0.8157	0.8273
	AIC	0.9636	4.7402	2.9660
	BIC	1.1225	5.0580	3.2043

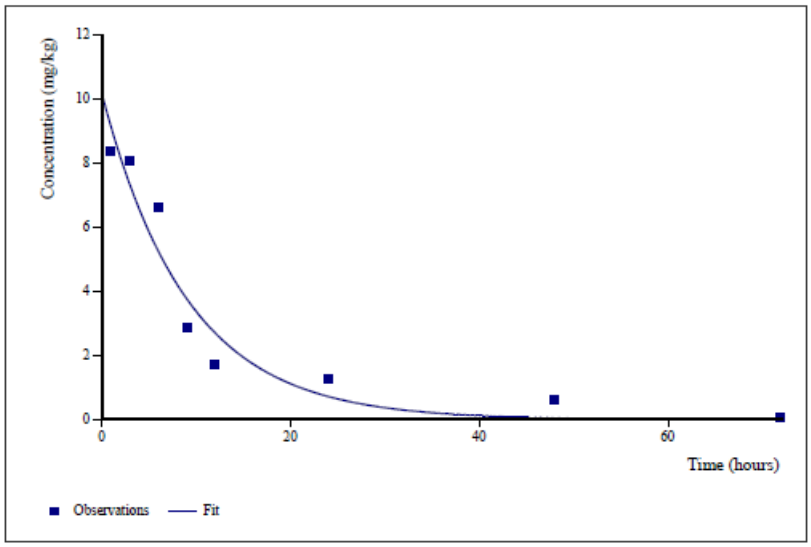


Figure 2.1. Observations and Fitted Model: SFO

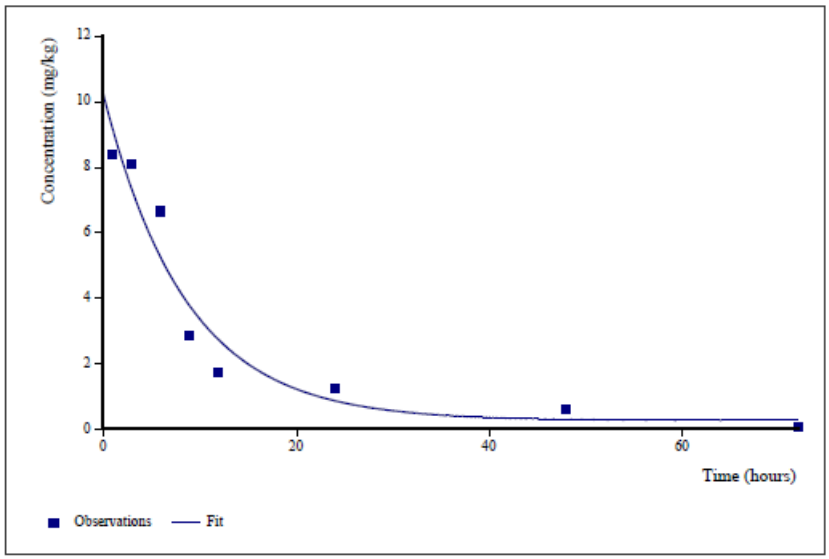


Figure 2.5. Observations and Fitted Model: DFOP

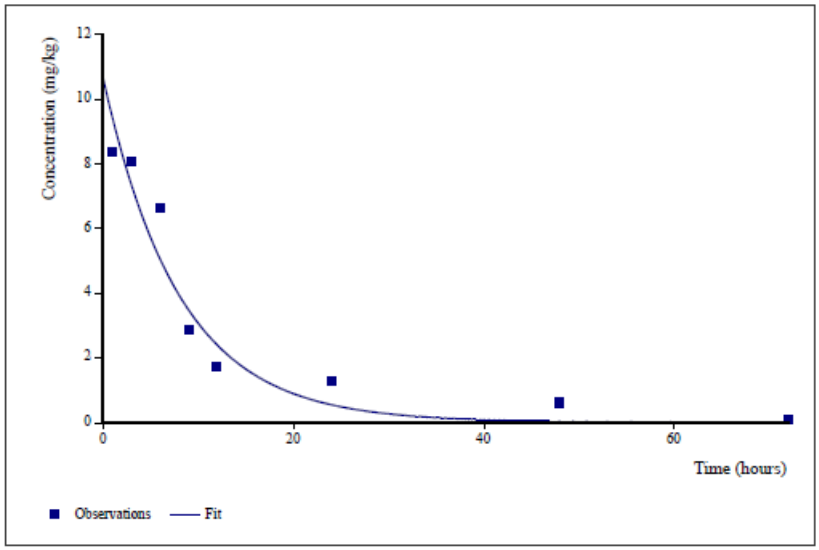


Figure 2.9. Observations and Fitted Model: FOMC

Conclusion: All 3 models have a Ch^2 error score above 15% and the lowest score was found for the SFO model. The parameter k of this model is highly significant ($p<0.01$) and the 95% confidence interval ranges from 0.0566 to 0.1640. In the case of the DFOP and FOMC models, non-significant coefficients and confidence intervals covering the value "0" were found, i.e. they are useless. According to the information criteria, the lowest scores also apply to the SFO model. For the SFO model, the estimated value of DT_{50}=6.28 hours and DT_{90}=20.9 hours.
zRMS comment: Accepted.

3 TRIAL 19SGS10-03

Table 3.1. Value, Predicted Value and Residual

Time (hours)	Value (mg/kg)	SFO		DFOP		FOMC	
		Predicted Value	Residual	Predicted Value	Residual	Predicted Value	Residual
1	19.33	19.95	-0.6205	19.95	-0.6205	19.95	-0.6214
3	15.48	16.6	-1.124	16.6	-1.124	16.6	-1.123
6	15.6	12.61	2.993	12.61	2.993	12.61	2.995
9	11.13	9.572	1.558	9.572	1.558	9.571	1.559
12	4.68	7.267	-2.587	7.267	-2.587	7.267	-2.587
24	1.24	2.415	-1.175	2.415	-1.175	2.417	-1.177
48	0.35	0.2667	0.08331	0.2667	0.08328	0.2684	0.08164
72	0.19	0.02945	0.1606	0.02949	0.1605	0.02992	0.1601

Table 3.2. Estimeted Values model SFO, DFOP, FOMC

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
SFO $C_t = C_0 e^{-kt}$							
C_0	21.87	1.921	N/A	18.14	25.6	17.17	26.57
k	0.09181	0.01671	0,0008	0.05933	0.1243	0.05091	0.133
DFOP $C_t = C_0 g e^{-k_1 t} + C_0(1-g)e^{-k_2 t}$							
C_0	21.87	2.468	N/A	16.61	27.13	15.02	28.72
k_1	0.09181	0.05087	0.07273	-0.01665	0.2003	-0.04944	0.233
k_2	6.29E-013	3.45E+003	0.5	-7361	7.36E+003	-9587	9.59E+003
g	1	0.3477	N/A	0.2587	1.741	0.03459	1.965
FOMC $C_t = C_0 / [(t/\beta) + 1]^{\alpha}$							
C_0	23.13	2.183	N/A	18.73	27.53	17.52	28.74
α	1.30E+003	687.2	N/A	-87.4	2.68E+003	-469.2	3.06E+003
β	1.20E+004	7.14E+003	N/A	-2339	2.64E+004	-6306	3.04E+004

Table 3.3. Goodness of Fit

		SFO	DFOP	FOMC
Chi^2	Error %	15.3	17.6	16.3
	df	6	4	5
Decay Times	DT50 (hours)	7.55	7.55	6.44
	DT90 (hours)	25.1	25.1	21.4
Goodness of fit	R^2 (Obs v Pred)	0.9507	0.9507	0.9507
	Efficiency	0.9504	0.9504	0.9503
	Współczynnik korelacji	0.9751	0.9751	0.9751
	Relative mean squared error	3.7837	3.7717	3.6462
	Relative average deviation	0.8881	0.8870	0.8745
	MAE	1.2867	1.2867	1.2868
	MPE [%]	-2.3767	-2.3793	-2.4874
	MAPE [%]	37.7429	37.7403	37.6726
	MSE	2.6390	2.6390	2.6399
	RMSE	1.6245	1.6245	1.6248
	AIC	11.7633	15.7633	13.7661
	BIC	11.9221	16.0810	14.0044

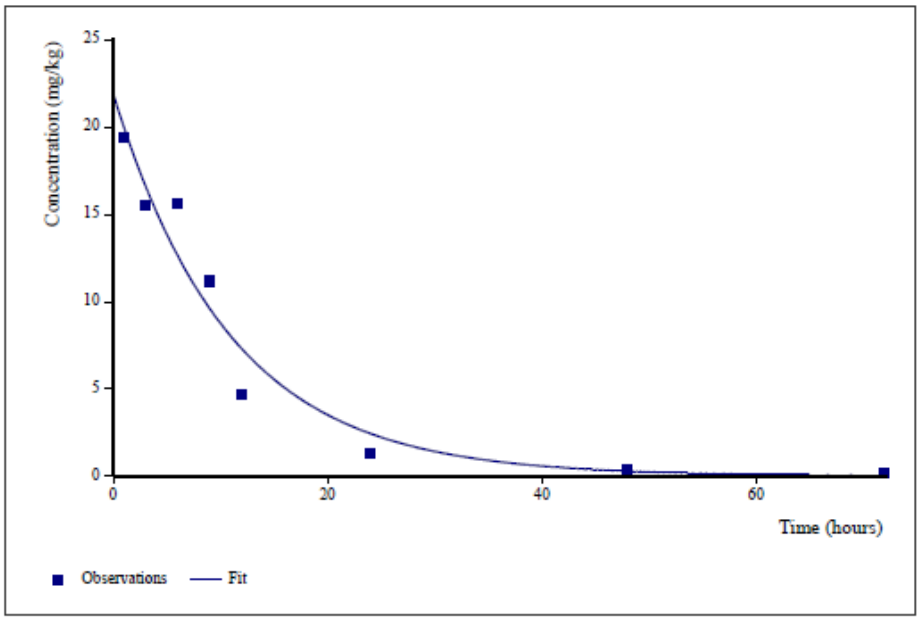


Figure 3.1. Observations and Fitted Model: SFO

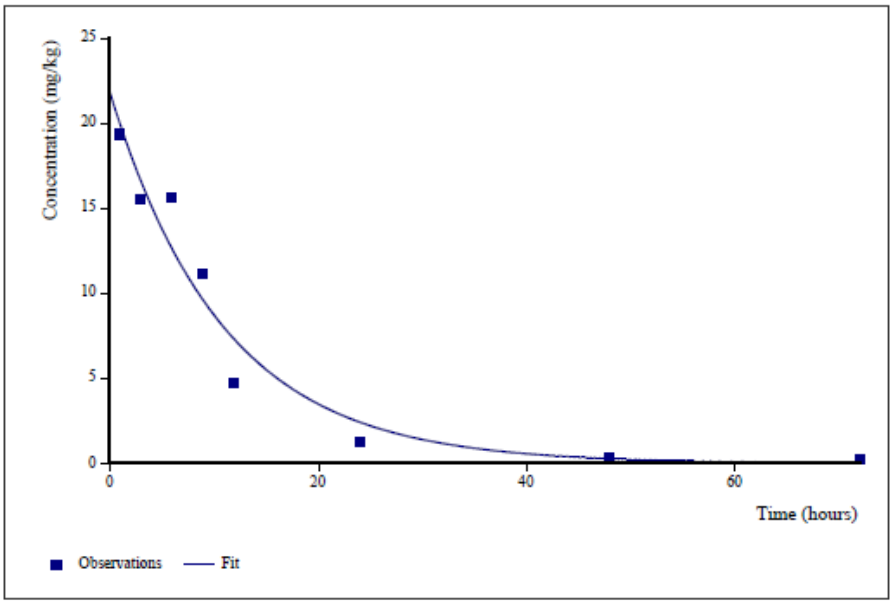


Figure 3.5. Observations and Fitted Model: DFOP

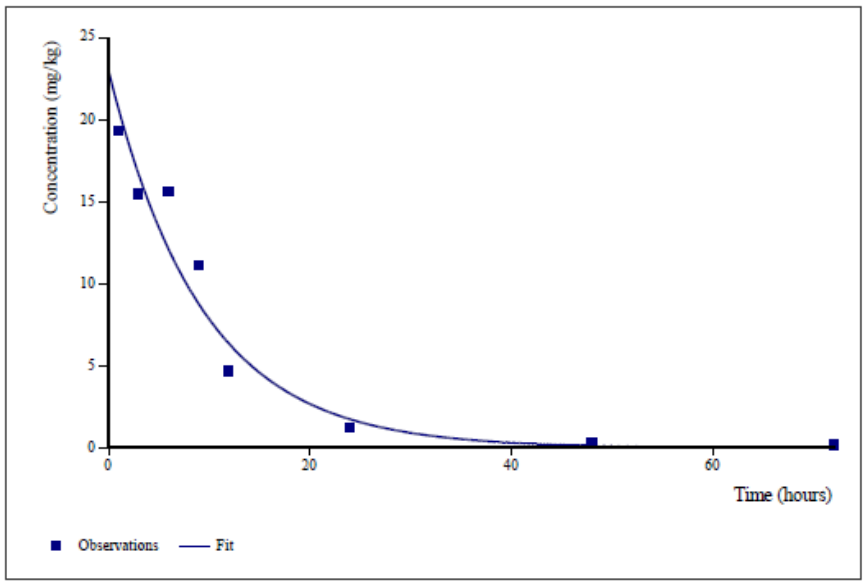


Figure 3.9. Observations and Fitted Model: FOMC

Conclusion: All 3 models have a Ch^2 error score above 15% and the lowest score was found for the SFO model. The parameter k of this model is highly significant ($p<0.01$) and the 95% confidence interval ranges from 0.05091 to 0.133. In the case of the DFOP and FOMC models, non-significant coefficients and confidence intervals covering the value "0" were found, i.e. they are useless. According to the information criteria, the lowest scores also apply to the SFO model. For the SFO model, the estimated value of DT_{50}=7.55 hours and DT_{90}=25.1 hours.
zRMS comment: Accepted.

4 TRIAL 19SGS10-04

Table 4.1. Value, Predicted Value and Residual

Time (hours)	Value (mg/kg)	SFO		DFOP		FOMC	
		Predicted Value	Residual	Predicted Value	Residual	Predicted Value	Residual
1	6.4	6.974	-0.5735	6.974	-0.5735	6.974	-0.5742
3	6.41	6.468	-0.05829	6.468	-0.05828	6.469	-0.05848
6	6.05	5.778	0.2718	5.778	0.2718	5.778	0.2721
9	5.03	5.162	-0.1317	5.162	-0.1317	5.161	-0.1311
12	5.39	4.611	0.779	4.611	0.779	4.61	0.7798
24	3.38	2.936	0.4437	2.936	0.4437	2.936	0.4442
48	0.18	1.191	-1.011	1.191	-1.011	1.192	-1.012
72	0.058	0.4829	-0.4249	0.4829	-0.4249	0.4841	-0.4261

Table 4.2. Estimeted Values model SFO, DFOP, FOMC

Parameter	Value	s	Prob. > t	Lower (90%) CI	Upper (90%) CI	Lower (95%) CI	Upper (95%) CI
SFO $C_t = C_0 e^{-kt}$							
C_0	7.241	0.4625	N/A	6.342	8.139	6.109	8.372
k	0.03761	0.006752	0.0007	0.02449	0.05073	0.02109	0.054
DFOP $C_t = C_0 g e^{-k_1 t} + C_0(1 - g)e^{-k_2 t}$							
C_0	7.241	0.5283	N/A	6.114	8.367	5.774	8.708
k_1	0.03761	0.01543	0.03573	0.004705	0.07051	-0.005244	0.08
k_2	0.03761	0.004803	7.18E-004	0.02737	0.04785	0.02427	0.051
g	0.2014	nd	N/A	nd	nd	nd	nd
FOMC $C_t = C_0 / [(t/\beta) + 1]^{\alpha}$							
C_0	7.699	0.578	N/A	6.534	8.864	6.213	9.185
α	927.5	211.7	N/A	501	1.35E+003	383.5	1.47E+003
β	1.91E+004	3.59E+003	N/A	1.19E+004	2.64E+004	9.91E+003	2.84E+004

Table 4.3. Goodness of Fit

		SFO	DFOP	FOMC
Chi^2	Error %	10.7	12.3	11.4
	df	6	4	5
Decay Times	DT50 (hours)	18.4	18.4	14.3
	DT90 (hours)	61.2	61.2	47.6
Goodness of fit	R^2 (Obs v Pred)	0.9562	0.9562	0.9561
	Efficiency	0.9506	0.9506	0.9505
	r	0.9778	0.9778	0.9778
	Relative mean squared error	0.1945	0.1945	0.1946
	Relative average deviation	0.2766	0.2766	0.2767
	MAE	0.4619	0.4619	0.4623
	MPE [%]	-159.3333	-159.3333	-159.6585
	MAPE [%]	167.3544	167.3544	167.6843
	MSE	0.3039	0.3039	0.3044
	RMSE	0.5512	0.5512	0.5517
	AIC	-5.5295	-1.5295	-3.5148
	BIC	-5.3706	-1.2117	-3.2765

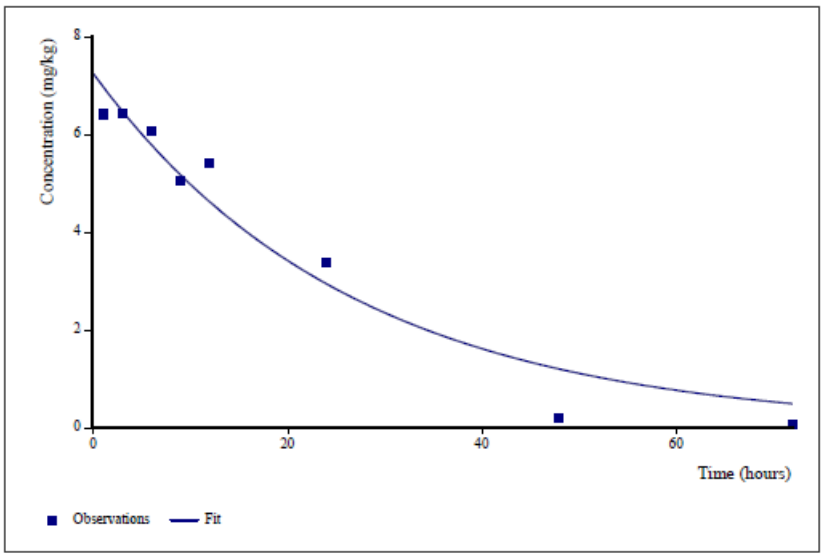


Figure 4.1. Observations and Fitted Model: SFO

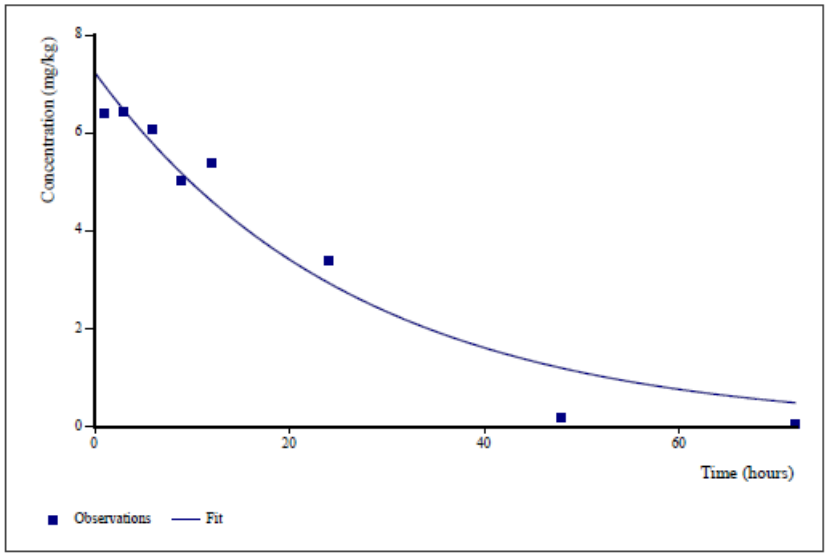


Figure 4.5. Observations and Fitted Model: DFOP

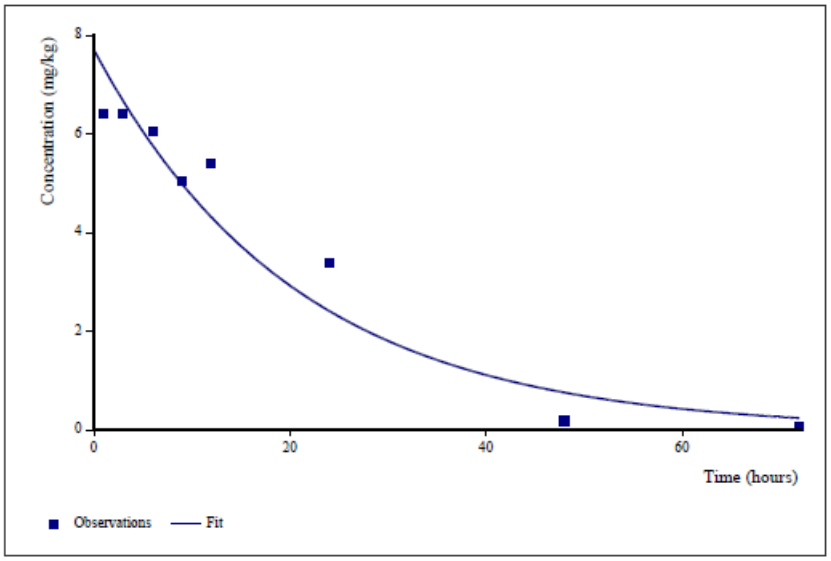


Figure 4.9. Observations and Fitted Model: FOMC

Conclusion: All 3 models have Ch^2 error below 15% and the lowest result was found for the SFO model, i.e. Ch^2 error is 10.7%. All 3 models have a similar goodness of fit to the data with a high coefficient of determination and a similar error rate, so the complexity issues will determine the choice of model. According to the information criteria, the lowest scores also apply to the SFO model. The parameter k of this model is highly significant ($p<0.01$) and the 95% confidence interval ranges from 0.0210 to 0.0540. For the SFO model, the estimated value of DT_{50}=18.4 hours and DT_{90}=61.2 hours.
zRMS comment: Accepted.

A higher tier risk assessment based on the refinement parameters such as foliage residue dissipation (DT_{50}) was accepted by RMS.

Study limitations:
1. in this case we have two studies located very close each other – Piskorzówek and Grodków – the distance is 37 km. According to the guidelines, it is recommended to use a minimum of 4 locations.

Trial 19SGS10-01 located in Piskorzówek, postal code: 55-216 (GPS coordinates N 50°54'14", E

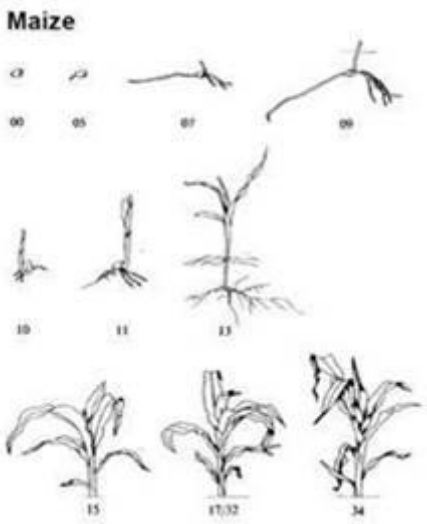
17°8’51,4) according to topography map, was located 143,1 m above sea level. Trial 19SGS10-02 located in Grodków, postal code: 49-200 (GPS coordinates N 50°41’3,5”, E 17°21’5,4”) was located 176 m above sea level. On the map we can see that sum of precipitation on year 2019 is also different in trials. For trial 19SGS10-01 it is 500-600 mm, for trial 19SGS10-02 it is 400-500 mm.

Main differences between trials:

Trial	19SGS10-01	19SGS10-02
Variety	Figaro	Topaz
Sowing date	26.04.2019	01.06.2023
Soil characterisation	Sand - 19%; Silt 61%; Clay - 20%	Sand - 24%; Silt 65%; Clay - 11%
Soil Organic Matter	3,1%	1,9%
Soil pH	7,3 (water)	6,8 (KCl)

According Technical Report EFSA 2019 one identified geographical location where a specific experiment is carried out. Sites are characterized by unique geo climatic conditions. No clear boundaries can be set for site identification/separation. However, two sites should be considered independent if they are at sufficient geographical distance to allow some difference in the geo-climatic conditions. As a rule of thumb, ≈ 100km is considered a sufficient distance (but in this case we have two studies located very close each other – Piskorzówek and Grodków – the distance is 37 km. *In opinion zRMS in this case due to some differences in the height of the area above sea level, differences in rainfall and soil organic matter smaller geographical distances can still be appropriate.*

2. In the studies applications were performed at 12-13 BBCH crop stage (2-3 leaves unfolded). In GAP is 12-18 BBCH crop stage (Stages continuous till 9 or more leaves unfolded). Please justify as crop interception in the earlier phase of BBCH 12-13 maize will be less. However, in opinion zRMS the small difference in biomass and tested growth stages does not represent a principal deficiency of the study that would justify a complete rejecton of the data. In maize at early growth stages plant size (biomass) is not considered to represent the most crucial parameter for the decline of residues. At the study start first of all active substance concentration on the plant are related only to the use rate (compound per ha) and thus are independent from the actual growth stage; in this case the dose is the same as in GAP. The process of residue decline (DT_{50}) is independent from the concentration at start of the study. On the other hand It is correct that plant growth may lead to a kind of,, residue dilution ‘’. Taking this into account, the BBCH 12-13 phase can be considered acceptable in this case.



The method is acceptable in section B5. The analytical method meets the requirements of guideline SANTE/2020/12830, Rev.1. A kinetic statement on the determination of DT_{50} for mesotrione in accordance with current guidelines has been submitted and accepted by zRMS. The DT_{50} = 0.56 d as arithmetic mean was proposed by Applicant. However, according to the harmonization arrangements for Poland, when the tests include 4 - 9 locations - maximum values can be used $DT_{50.}$ The worst case is DT_{50} = 0.9 d and this value should be used in risk assessment. Estimated new f_{TWA} = 0,062 based on residue decline study will be used as a risk refinement for reproductive risk to mammals in post-emergence use. MAFm * TWA (refined DT_{50}) = 0.062 should be used in risk assessment.

Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of Mezot 100 SC in Maize – refined parameters

Reprod. toxicity (mg/kg bw/d), NOEL		0.3				
TER criterion		5				
Intended use		Maize				
Application rate of a.i. (kg/ha)		1 x 0,150				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**$MAF_m \times f_{TWA}$**	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize (BBCH 10-19)	Small insectivorous mammal "shrew"	4.2	~~1,0 x 0,038~~ 1,0 x 0,062	~~0,139~~ 1	~~0,003~~ 0.03906	~~91~~ 7.68
Maize (BBCH 10-29)	Small herbivorous mammal "vole"	72.3	~~1,0 x 0,038~~ 1,0 x 0,062	~~0,139~~ 1	~~0,0573~~ ~~0.67239~~	~~5,24~~ **0.45**
Maize (BBCH 10-29)	Small omnivorous mammal "mouse"	7.8	~~1,0 x 0,038~~ 1,0 x 0,062	0,139	~~0,0062~~ 0.01	~~48~~ 30

According to Peer review of the pesticide risk assessment of the active substance mesotrione (EFSA Journal 2016;14(3):4419) for risk refinement, a range of studies were available for identification of specific focal species and PT values. The omnivorous wood mouse (*Apodemus sylvaticus*) and the herbivorous European brown hare (*Lepus europaeus*) were considered appropriate focal species for maize at the early stages after germination (BBCH 10-16). zRMS comment: Based on the new f_{TWA}, application for vole is still unacceptable. However, based on EFSA Conclusion 2016 voles are not representative species in maize. The focal species for maize at early BBCH growth stages such as wood mouse and brown hare were accepted by zRMS.

Refined PT value for brown hare was adopted based on study:

Title	Generic monitoring of European hares in Central Europe to determine the proportion of time spent foraging in early maize.
Study code	RIFCON GmbH Report No. R1740065
Study director	I. Katzschner
Study complection date	21 December 2018
Quality	The study was conducted in compliance with: • Principles of Good Laboratory Practice — German Chemical Law (Chemikaliengesetz), dated 28 August 2013, revised 18 July 2017, current version of Annex 1 • The current OECD Principles of Good Laboratory Practice (GLP), ENV/MC/Chem(98)17: Environmental Health and Safety Publications. Environment Directorate, Organisation for Economic Co-operation and Development, Paris (1998) • OECD Guidance document ENV/JM/MONO(2002)9: The Application of

	the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies; OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring (No. 13), OECD Environment, Health and Safety Publications. Environment Directorate, Organisation for Economic Co-operation and Development, Paris (2002) • OECD Guidance document ENV/JM/MONO(99)22: The Application of the GLP Principles to Field Studies; OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring (No. 6 [revised]); OECD Environment, Health and Safety Publications. Environment Directorate, Organisation for Economic Co-operation and Development, Paris (1999)

Summary:
The aim of this generic study was to investigate hares (Lepus europaeus) that use maize fields as foraging habitat in Central Europe. Respective PT values (i.e. proportion of diet obtained in treated area; calculated as proportion of potentially foraging time spent in maize fields) were determined during the early growing period of maize via continuous 24h radio-tracking sessions of several individual hares.

Material and Methods:
The study was conducted in two different study sites in Central Europe in typical areas for maize growing with maize proportions of on average 38%. The study sites were located near Essen (Oldenburg) in Lower Saxony (Germany) and near Bösárkány in the administrative county of Győr-Moson-Sopron (Hungary).
Each study site, comprising the areas around the trapping locations of the tagged individuals as well as locations determined during 24h telemetry and single check telemetry, was mapped for habitat types with special emphasis on single crop types. The vegetation status of maize in the study sites was recorded via respective BBCH growth stages.

The animals were trapped and equipped with radio tags at the beginning of the Field Phase, and before the drilling period of maize. To ensure the availability of maize within the home range of the tracked individuals, hares were captured either on future maize fields or nearby (e.g. in off-crop structures around future maize fields).
Hares were trapped using series of nets. The animals were chased into the nets by drivers walking towards the nets.
Each trapped animal was sexed, weighed and equipped with a radio tag (Biotrack Ltd., UK; www.biotrack.co.uk) and released at the trapping site.

For radio-tracking, animals were located with Yagi antennas following to two different approaches: 24h telemetry and single check telemetry. During 24h telemetry the animal was radio-tracked continuously (for 24 hours) by two observers, locating the animal from two different positions, which allowed to triangulate the animal's exact position.
Each change of habitat (if possible) and/or of behaviour (i.e. active/inactive) was recorded with time (exact to the minute) and bearing angle to the signal of the animal. The 24h telemetry sessions covered the BBCH growth stages < 20. Main focus was given to the period of leaf development (i.e. BBCH growth stages 10 to 19).
During single check telemetry each animal was located at least once at the beginning and the end of the overall radio-tracking period in order to survey its presence in the study site during the entire Field Phase.
In order to confirm the animal's behaviour based on the radio signals, animals were observed with binoculars, scopes and night observation devices to get 'visual contact' whenever possible.

Calculation of PT:
For each 24h telemetry session the diet obtained in maize fields (PT) was calculated as the proportion of the 'potential foraging' time the individual hare spent in that crop. The 'time potentially foraging' is the sum of the time periods covered by behavioural categories when foraging could not be excluded. All instances when the animal was definitely known to be performing non-foraging activities (e.g. resting or fighting) were excluded from PT calculations.
A mean PT value (plus standard deviation and 90th percentile values) was calculated based on single PT values. In addition, the total visual contact time during 24h telemetry was calculated.

Results:
In total, radio-tracking sessions of 15 individual hares at two study sites were performed during the early crop development of maize in Central Europe. Radio-tracking sessions were performed in May 2018 and covered the maize BBCH growth stages <20. The number of analysed 24h telemetry sessions was 17 (eight in Germany, nine in Hungary), since two individuals were radio-tracked twice for 24 hours.
Each session was considered as 'consumer session' because in 16 out of 17 analysed sessions the hare was recorded being potentially foraging in a maize field during the session. Each hare was trapped in a future maize field or close by and all hares had maize within the 24h home range (MCP 100%).
The calculated PT values ranged from 0.00 to 0.94. Calculated PT values did not differ substantially between different study sites; mean values were slightly higher in Hungary (0.35) compared to Germany (0.29). Also PT values between the sexes did not differ substantially even though mean values were slightly higher in male hares (0.39) than in female hares (0.26).
Regarding BBCH growth stages, hares tended to spend more potentially foraging time inside maize fields during 24h tracking sessions containing fields with BBCH growth stages 15 or higher inside the home range. In tracking sessions in which maize fields of later BBCH growth stages (i.e. BBCH growth stage ≥15) were part of the home range, the mean PT value was 0.48, whereas the mean PT value in sessions including only maize fields of early BBCH growths stages (i.e. BBCH growth stage <15) within the home range was 0.20.

PT values of hares in maize fields at early BBCH growth stages (BBCH growth stages <20) in Central Europe:

Country	Session ID	PT	Date (dd.mm.yyyy)
Germany	GER_399_01	0.04	08.05.2018
	GER_399_02	0.17	09.05.2018
	GER_399_03	0.24	11.05.2018
	GER_399_04	0.03	13.05.2018
	GER_399_05	0.32	15.05.2018
	GER_399_06	0.36	16.05.2018
	GER_399_07	0.09	18.05.2018
	GER_399_08	0.94	25.05.2018
Hungary	HU_399_01	0.16	03.05.2018
	HU_399_02	0.32	05.05.2018
	HU_399_03	0.03	07.05.2018
	HU_399_04	0.60	08.05.2018
	HU_399_05	0.00	09.05.2018
	HU_399_06	0.28	11.05.2018
	HU_399_07	0.56	13.05.2018
	HU_399_08	0.43	14.05.2018
	HU_399_09	0.74	16.05.2018
Mean		**0.31**	-
90th percentile		**0.66**	-
Standard Deviation		**0.27**	-

The total visual contact time during all 24h telemetry sessions was 25 hours and 59 minutes. This reflects 6.4% of the total radio-tracking time of 408 hours. The observed behaviours during visual contact were 53.4% resting, 19.8% foraging behaviour, and 26.9% other behaviour (such as e.g. fighting, running or grooming).

Conclusion:
According to recommendations of EFSA (2009) regarding PT studies, this report gives reliable and robust PT values for the European hare using maize fields during early growth stages in Central Europe for use in wildlife risk assessments. Hares did not use maize fields as foraging habitat to more than on average 31% (90th percentile 66%) even though maize fields presented the most abundant crop at both study sites. Values were calculated under worst case assumptions and the PT values are considered to be conservative.

Refined PT value:

- The PT value of 0.139 for wood mouse was accepted at the EU level during mesotrione evaluation, based on study Grimm T., Dietzen C & von Blanckenhagen F (2013): Generic field study on small mammals focal species and wood mouse (Apodemus sylvaticus) PT in maize fields in Germany, Report P12225
- The PT value of 0.66 for brown hare, based on study Generic monitoring of European hares in Central Europe to determine the proportion of time spent foraging in early maize, Katzschner, I. and Grimm, T. (2018), Report No: R1740065.

zRMS agrees with the refined PT value (PT = 0.139) for wood mouse and PT value (PT = 0.62) for brown hare. The refined PD value (0.84 – maize shoots and 0.16 – dicot weeds) for Brown hare was reject by zRMS.

The refinement risk assessment for mammals was corrected by zRMS.

Intended use	Maize					
Active substance/product	Mesotrione					
Application rate (g a.s./ha)	1 × 150					
Reprod. toxicity (mg/kg bw/d)	0.3					
TER criterion	5					
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**PT**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize BBCH 10-29	Brown hare *Lepus europaeus* (100% grass)	17.3[1)]	0.62	1 x 0.062	0.09975	**3.0**

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

1) SVm from EFSA B&M guidance (2009) for Brown hare (grassland scenario)

Intended use	Maize					
Active substance/product	Mesotrione					
Application rate (g a.s./ha)	1 × 150					
Reprod. toxicity (mg/kg bw/d)	0.3					
TER criterion	5					
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**PT**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize BBCH 10-29	*Apodemus sylvaticus*	7.8[1)]	0.139	1 x 0.062	0.01	30

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

1) SVm from EFSA B&M guidance (2009) for Brown hare (grassland scenario)

Based on the new f_{TWA} and refinement PT value - application for brown hare is still unacceptable, therefore refinement of reproductive risk assessment for the herbivorous brown hare (*Lepus europaeus*) and the small omnivorous for Rabitt exposed to Mesotrione based on refined NOEAL of 1.2 mg a.s./kg bw.

Justification: The information available in the mesotrione RAR of 2015 (Vol. 3CA, B.6) indicates that in fact, slightly reduced pup survival at 10 ppm (1.2 mg a.s./kg bw/d) was incidental and not treatment related, as at the next higher dose (100 ppm) the pup survival was at the level comparable with control values. For this reason it seems that for purposes of the ecological risk assessment NOAEL of 1.2 mg a.s./kg bw/d could be considered relevant and was actually proposed by the RMS (UK).

Mesotrione effects on F1 generation from the multigeneration study in rats (RAR (2015))

Parameter	**Generation**	**Dose Level (ppm)**				
		0	**2.5**	**10**	**100**	**2500**
Gestation length (d)	F1	22.3	22.3	22.4	22.8**	22.9**
Litter size (no. pups)	F1	11.7	12.4	10.9	10.3	9.2**
Litter weight (g) Day 0	F1	70.4	72.2	65.9	63.4	57.1**
Pup survival (%)	F1	92.4	89.9	85.2**	89.7	77.6**

* significantly different to control ($p<0.05$), ** ($p<0.01$)

Conclusion: F1 results indicate a clear effect at dose levels of 2500 ppm, with all results being significantly different to the control. A reduction in litter size by 6.8% is seen in animals treated at 10 ppm and by 11.1% for those treated at 100 ppm when compared to the control group. Litter weight is similarly reduced at these doses, but this effect is a consequence of the reduced litter size. A significant reduction in pup survival is seen at 10 ppm but this is not dose-related and is therefore not considered to be of toxicological concern. Based on F1 developmental data, a NOAEL of 10 ppm (1.2 mg/kg bw/d) is therefore proposed. It is here proposed to use the NOAEL of 10 ppm (corresponding to 1.2 mg/kg bw/d) from the F1 generation data, being in more relevant in the ecotoxicology risk assessment because of the use pattern of mesotrione (it is applied once per season, thus results from the single generation are more appropriate than results from a second generation after more than 20 weeks of exposure) and results from different generations indicate that mesotrione effects were not the result of exposure during a critical developmental phase. On the other hand this issue was discussed at Pesticides Peer Review experts Meeting 136 in December 2015, where it was decided that the observed effects (e.g., litter size and pup survival) on the F2 generation should not disregard.

Higher-tier assessment of the long term risk for mammals due to the mesotrione use of MEZOT 100 SC in maize based on reduced dose

\Intended use		maize
Active substance/product		mesotrione
Application rate (g/ha)		1 × 150
Reprod. toxicity (mg/kg bw/d)		1.2
TER criterion		5

Crop scenario Growth stage	**Indicator/generic focal species**	**Fir/bw**	**RUD**	**SV_m**	**MAF_m × TWA**	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize	Rabbit (100 % plant material)	0.334	54.2	-	0.062	0.62	0.1	12

*In grey verified by RMS based on DT_{50} of 0.9d.

The trigger value for rabbit and *Apodemus sylvaticus* are above the trigger of 5.
Therefore, further refinement is not required for this species as the TERLT is above the trigger of 5 indicating acceptable risk to mammals.

Based on the risk refinement based on refinement toxicity endpoints, F_{twa} value and PT value it can be concluded that application of **MEZOT 100 SC** according to the label will not pose no unacceptable reproductive risk to mammals.

zRMS comment: The risk for mammals due to exposure to mesotrione via contaminated drinking water in puddles was corrected by zRMS.

Puddle scenario
Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of 156, mesotrione belongs to the group of less sorptive substances.

Effective application rate (g/ha)*	=	150		
Acute toxicity (mg/kg bw)	=	5000	quotient =	0.03
Reprod. toxicity (mg/kg bw/d)	=	0.3	quotient =	**500**

With a K(f)oc of 14 (as a worst case), mesotrione belongs to the group of less sportive substances. Since the ratio of effective application rate (150 g/ha) to relevant endpoint (0.3 mg/kg bw/d) exceeds the critical value of 50 for at least one use scenario, a quantitative risk assessment (calculation of TER values) is necessary.

Assessment of the risk for mammals due to exposure to mesotrione via contaminated drinking water in puddles

Intended use	maize
Active substance	mesotrione
Application rate (g/ha)	1 x 150
Reprod. toxicity (mg/kg bw/d)	0.3
TER criterion	5

Soil-relevant applic. rate (g/ha)	**Koc (L/kg)**	**PEC_{puddle} (mg/L)**	**DW uptake (L/kg bw/d)**	**Daily dose (mg/kg bw/d)**	**TER_a** / **TER_{lt}**
150	50 (geomean)	0.158	0.24	0.0379	7.92
150	14 (worst-cse in Efsa conslusion)	0.366	0.24	0.0878	**3.42**

For the proposed use the resulting TER values are below the trigger of 5 (for K_{OC} wrost case value of 14) indicating unacceptable chronic risk to mammals from drinking water from puddles. Taking into account the refined NOAEL value 1.2 mg a.s./kg bw the TER reaches the acceptable value as presented in the following table:
Assessment of the risk for mammals due to exposure to mesotrione via contaminated drinking water in puddles

Intended use	miaze
Active substance	mesotrione
Application rate (g/ha)	1 x 150
Reprod. toxicity (mg/kg bw/d)	1.2
TER criterion	5

Soil-relevant applic. rate (g/ha)	Koc (L/kg)	PEC_{puddle} (mg/L)	DW uptake (L/kg bw/d)	Daily dose (mg/kg bw/d)	TER_a / TER_{lt}
150	14 (worst-cse in Efsa conslusion)	0.366	0.24	0.0878	13.66

zRMS comment: The refinement assessment of the risk for mammals due to exposure to mesotrione via contaminated drinking water in puddles use of a refinement of toxicity endpoint (NOAEL=1.2 mg/kg bw/d) demonstrated acceptable risk to mammals.

3.8.2 Effects on aquatic species

Risk assessments for Mezot 100 SC with the proposed use pattern were provided and considered adequate. The TER using worst-case PEC values for parent and metabolites, exceed the relevant triggers, indicating that these metabolites do not pose an unacceptable risk to aquatic organisms following applications of Mezot 100 SC according to the recommended use pattern.

According to mitigation measures (spray drift reduction), use of Mezot 100 SC cause accepted effect to aquatic organisms:

1. Maize - 20 m no-spray buffer zone.

The product was classified as:
Aquatic Acute 1; H400 – Very toxic to aquatic life
Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.

3.8.3 Effects on bees

An estimation of risk indicate low risk for bees of each range of assessed issues.
The acute risk to honeybees from use of Mezot 100 SC was assessed using the maximum single application rate and the LD_{50} values to calculate hazard quotients.
The HQs are below the trigger value showing an acceptable risk to bees from the proposed use of Mesotrione and therefore no further consideration is required.
For Poland authorisation of the product until EU GD for Bees, EFSA 2013, will be implemented and the test is not required according to Internal Harmonisation Meeting in Polish Ministry.

Additional studies were done:

- Mezot 100 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test
- Mezot 100 SC Honeybees (Apis mellifera L.), Larval Toxicity Test, Single Exposure.

3.8.4 Effects on other arthropod species other than bees

Risk assessment strategy used here follow recommendations in the ESCORT 2 guidance document (Candolfi et al. 2001) and opinion (EFSA Journal 2015;13(2):3996).

zRMS agrees with the Applicant's assessment with the in-field and off-field risk to non-target arthropods from the proposed use of **Mezot 100 SC** above, however the VDF is set to 5 in the Central zone instead of 10 for only 2-D studies (In this case in 3-D studies VDF correction is 1). A low risk is demonstrated to the 2 standard first tier.

Use of Mezot 100 SC indicate low risk for non-target arthropods other than bees.

3.8.5 Effects on soil organisms

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Mesotrione (plus certain metabolite) and Mezot 100 SC.
The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002). The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate) and data for metabolites from DAR for Mesotrione.

Risk assessment for macroorganisms other than earthworms
As stated in Commission Regulation EU No 284/2013 of 1 March 2013, "For plant protection products applied as a foliar spray, data on the relevant two non-target arthropod species might be taken into account for a preliminary risk assessment. If effects do occur on either species, testing on *Folsomia candida* and *Hypoaspis aculeifer* shall be required."

The formulated product **MEZOT 100 SC** is applied as a foliar spray treatment. As demonstrated above, acceptable risks are expected towards the earthworms and a low in-field and off-field risk is demonstrated for non-target arthropods - such as - *Typhlodromus pyri, Aphidius rhopalosiphi* (standard laboratory studies) in maize (1 x 150 g s.a./ha). On the other hand, all the long-term TER values are much higher than the trigger value of 5, indicating that Mezot 100 SC poses low acute risk also for earthworms. Therefore, the risk assessment for macroorganisms other than earthworms is not required.

All the long-term TER values are much higher than the trigger value of 5, indicating that **Mezot 100 SC** poses low acute risk to earthworms and macroorganisms other than earthworms (*Folsomia candida, Hypoaspis aculeifer*) when applied according to the proposed use rates (maize).

3.8.6 Effects on non-target terrestrial plants

Studies on the toxicity to non-target terrestrial plants have been carried out with Mesotrione. Full details of these studies are provided in the respective EU DAR.

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.
Use of Mezot 100 SC is accepted concerning effects on non-target terrestrial plants.
To protect non-target plants respect an unsprayed buffer zone of 5 m to non-agricultural land.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No studies submitted.

3.9 Relevance of metabolites (Part B, Section 10)

According to calculation of PECgw made by PELMO and PEARL Focus models, maximum concentration results of the metabolite MNBA show a very slight exceeded of the limit value only in one scenario (Hamburg).

Please refer to the second Addendum to DAR, Revision 2 (September 2001) for mesotrione for full details of the relevance assessment performed for both metabolites MNBA and AMBA according to the "Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater" (SAN-

CO/221/2000 rev. 10- 25 February 2003).

In brief, based on the classification of the parent active substance mesotrione and based on the available toxicological data on MNBA and AMBA, both metabolites MNBA and AMBA are con-sidered to be non-relevant metabolites in ground water.

Mesotrione does not require classification and labelling with respect to human health effects. It is not listed in Annex VI of the Regulation (EC) No 1272/2008, and during the EU evaluation of the active substance mesotrione according to Directive 91/414/EEC no classification and labelling re-garding human health effects was proposed.

A study in male rats showed that MNBA was metabolised in the gut to AMBA. Approximately 16% of the administered radioactivity was excreted in the urine, (~5% as MNBA and ~10% as AMBA), indicating either absorption of AMBA from the gut or absorption and subsequent metabolism of MNBA. MNBA was found to be of comparatively low acute toxicity, however this metabolite was identified as a potential skin sensitiser. Increased motor activity was seen in female rats in a 28-day study with MNBA, however this finding is considered to be equivocal. No effects were seen in males. Minor effects on bodyweight and food consumption were noted in males only in a 90-day study. Mild hypertyrosinaemia was also seen in males at dose levels of 650 and 3000 ppm, howev-er urinary phenolic acids were not increased at this dose level. No significant effects were seen on HPPD activity in vitro.

AMBA was found to be of low acute oral toxicity. No significant effects were seen on HPPD ac-tivity in vitro.

According to the criteria regarding ecotoxicological effects laid out in Guidance Document on Rel-evant Metabolites (SANCO/221/200-Rev.2 of October 1999) , MNBA and AMBA are not relevant metabolites (DAR, UK Addendum, Revision 2, September 2001) . In brief, MNBA and AMBA are classified as non-relevant metabolites in view of their lack in pesticidal activity, genotoxicity, and other toxicological properties. Consequently, the metabolites MNBA and AMBA are considered to be non-relevant metabolites in groundwater.

The same study summaries were compared and confirmed according to the criteria in the updated version of the Guidance (SANCO/221/2000 rev. 10- 2003).

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

Not required.

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

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Sekcja pozostałości:
Dodano: *NASTĘPSTWO ROŚLIN*
W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na polu można uprawiać jedynie kukurydzę.

Sekcja toksykologii: Należy dodać H361d, H373.

Sekcja skuteczności: Zmieniono listę zaakceptowanych chwastów oraz zmodyfikowano wrażliwość niektórych z nich. Dodano zapis nt. fitotoksyczności: *Fitotoksyczność nie może być wykluczona. Wrażliwość odmian powinna być skonsultowana z posiadaczem zezwolenia.* Dodano wpis dotyczący następstwa roślin: *Wszystkie możliwe uprawy następcze mogą być uprawiane w ramach zwykłej uprawy roślin bez orki.*

Posiadacz zezwolenia:
Elvita Sp. z o.o., ~~Różewo, 78-627 Różewo~~ 87-400 GOLUB-DOBRZYŃ, ul. DWORCOWA 4, tel. +48 67 260 07 02, kontakt@elvita.com.pl

Mezot 100 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
mezotrion (związek z grupy triketonów) – 100 g/l

Niebezpieczeństwo

H318	Powoduje poważne uszkodzenie oczu.
H361d	Podejrzewa się, że działa szkodliwie na dziecko w łonie matki.
H373	Może powodować uszkodzenie narządów <podać wszystkie znane narządy, których to dotyczy>poprzez długotrwałe lub powtarzane narażenie <podać drogę narażenia, jeśli udowodniono, że inne drogi narażenia nie stwarzają zagrożenia
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
P273	Unikać uwolnienia do środowiska
P280	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.
P305+P351+P33	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut.

8	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.
P314	W przypadku złego samopoczucia zasięgnąć porady/zgłosić się pod opiekę lekarza.
P310	Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem/ Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem.
P501	Zawartość/pojemnik usuwać do uprawnionych firm utylizacji odpadów.

OPIS DZIAŁANIA

Herbicyd, w postaci koncentratu w formie stężonej zawiesiny do rozcieńczania wodą, stosowany nalistnie.
Zgodnie z klasyfikacja HRAC substancja czynna mezotrion zaliczana jest do grupy F2.

DZIAŁANIE NA CHWASTY

Środek jest selektywnym herbicydem o działaniu układowym. Pobierany jest głównie poprzez liście oraz dodatkowo poprzez korzenie chwastów i szybko przemieszczany w roślinie, hamując jej wzrost i rozwój. Powoduje zahamowanie biosyntezy karotenoidów w roślinach chwastów, w następstwie czego następuje zniszczenie chlorofilu, objawiające się bieleniem liści. Pierwsze objawy działania

Srodka widoczne są po 5-7 dniach od wykonania zabiegu. Zamieranie chwastów następuje po około 14 dniach.
Środek stosować po wschodach chwastów w fazie 2-8 liści właściwych. Optymalną skuteczność działania uzyskuje się po zastosowaniu środka w fazie 4 liści właściwych.

Dawka 0,75 l/ha

Chwasty wrażliwe:	Komosa biała, ~~Przytulia czepna, Jasnota purpurowa,~~ Rdestówka powojowata, ~~Gorczyca polna,~~ Fiołek polny
Chwasty średniowrażliwe:	Chwastnica jednostronna, Tobołki polne

Dawka 1,5 l/ha

Chwasty wrażliwe:	~~Rumian polny, Perz właściwy, Szarłat szorstki,~~ Tasznik pospolity, Komosa biała, Chwastnica jednostronna, ~~Wilczomlecz, Dymnica pospolita,~~ Przytulia czepna Przytulia błotna, Jasnota purpurowa, ~~Maruna bezwonna,~~ Rdestówka powojowata, Gorczyca polna, ~~Psianka czarna,~~ Gwiazdnica pospolita, Tobołki polne, Fiołek polny

STOSOWANIE ŚRODKA

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

Kukurydza

Termin stosowania środka: środek stosować w fazie 2-8 liści kukurydzy (BBCH12-

18). Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,5 l/ha.
Zalecana dawka dla jednorazowego zastosowania: 0,75 - 1,5 l/ha.

Maksymalna liczba zabiegów w sezonie wegetacyjnym:
1. Zalecana ilość wody: 200 – 300 l/ha.
Zalecane opryskiwanie: średniokropliste.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

NASTĘPSTWO ROŚLIN
Wszystkie możliwe uprawy następcze mogą być uprawiane w ramach zwykłej uprawy roślin bez orki.
W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na polu można uprawiać jedynie kukurydzę

1. Środka nie stosować:
   - bez uprzedniego sprawdzenia wrażliwości na środek,
   - na rośliny osłabione lub uszkodzone przez szkodniki, przymrozki, zalanie lub suszę,
   - przed opadami deszczu,
   - podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.
2. Podczas stosowania środka nie dopuścić do:
   - znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
   - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

3. Strategia zarządzania odpornością.

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów, herbicydy powinny być stosowane zgodnie z Dobrą Praktyką Rolniczą:
- postępuj zgodnie z zaleceniami zawartymi w etykiecie środka ochrony roślin – stosuj środek w zalecanej dawce w terminie zapewniającym najlepsze zwalczanie chwastów,
- dostosuj zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
- używaj różnych metod kontroli zachwaszczenia w tym rotację upraw, itp.,
- stosuj rotacje herbicydów o różnym mechanizmie działania,
- stosuj mieszanki herbicydów o odmiennym mechanizmie działania,
- stosuj w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów,
- stosuj herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
- informuj posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,
- w celu uzyskania szczegółowych informacji skontaktuj się z doradcą, posiadaczem zezwolenia dla środka lub przedstawicielem posiadacza.

4. Fitotoksyczność nie może być wykluczona. Wrażliwość odmian powinna być skonsultowana z posiadaczem zezwolenia.
5. Przed użyciem upewnić się, że sprzęt do oprysku oczyszczono z poprzednich środków i skalibrowano, by móc stosować zalecaną objętość i ciśnienie natrysku. Należy upewnić się, że dysze opryskowe działają jednakowo, a belkę ustawiono na właściwą wysokość ponad uprawę.

Natychmiast po użyciu należy dokładnie wyczyścić sprzęt natryskowy i pozostałe. W czasie czyszczenia nie dopuścić, by produkt lub ciecz wypłukana ze sprzętu zanieczyściła wodę. Nie czyścić użytego sprzętu w pobliżu wód powierzchniowych. Unikać zanieczyszczania poprzez odpływy z placów i dróg.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Stosować środek w ilości 0,75–1,5 litra na ha w 200–300 litrach wody na hektar. Wybrać najlepszą ilość wody z zalecanego zakresu, aby uzyskać równomierne i dobre pokrycie ulistnienia chwastów. Jeśli to możliwe, stosować minimalną ilość wody (200 litrów na ha) — większa objętość (300 litrów na ha) może być wymagana, jeśli ulistnienie chwastu jest gęste. Nie przekraczać maksymalnej zalecanej objętości wody.

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem, zużyć w ciągu max. 24 godz. od sporządzenia.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Wypełnić zbiornik do połowy czystą wodą i rozpocząć łagodne mieszanie. Zawartością opakowania przed użyciem wstrząsnąć. Dodać wymaganą ilość produktu do zbiornika i odczekać, aż zostanie w pełni zdyspergowany. Opróżnione opakowania przepłukać trzykrotnie wodą za pomocą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać Nie przerywać mieszania aż do zużycia mieszaniny.

Oprysk prowadzić natychmiast po wymieszaniu. Nie pozostawiać cieczy użytkowej w urządzeniu do oprysku.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej 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.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

Resztki preparatu pozostające w sprzęcie do oprysku mogą uszkodzić inne uprawy opryskiwane tym samym sprzętem w późniejszym terminie. Natychmiast po użyciu należy dokładnie wyczyścić opryskiwacz i pozostałe elementy. Istotne jest, by wszystkie dysze, filtry, węże, sita, pompy i sam zbiornik zostały dokładnie wyczyszczone, aby uniknąć ryzyka zniszczenia upraw opryskiwanych później tym samym sprzętem.

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, odzież ochronną oraz ochronę oczu i twarzy zabezpieczające przed oddziaływaniem środków ochrony roślin podczas przygotowywania cieczy roboczej oraz rękawice ochronne i odzież roboczą podczas wykonywania zabiegu.

Stosować rękawice ochronne podczas pracy w obszarach, które miały kontakt ze środkiem. Zanieczyszczonej odzieży ochronnej nie wynosić poza miejsce pracy.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

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

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20 m od zbiorników i cieków wodnych.
W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

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

30°C. Chronić przed mrozem.

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 kontaktu ze skórą: umyć dużą ilością wody z mydłem.
W przypadku dostania się do oczu: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. Natychmiast skontaktować się z ośrodkiem zatruć lub lekarzem.
W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Termin ważności - 2 lata Data produkcji Zawartość netto
Nr partii

Appendix 3 Letter of Access

Letter of access is enclosed.

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 protec-tion claimed Y/N	Justification if data protection is claimed	Owner
3.2.3	Grabiński, J.	2019	Badanie skuteczności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 02/19, Report I GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Grabiński, J.	2019	Badanie skuteczności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 02/19, Report II GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Grabiński, J.	2019	Badanie skuteczności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 02/19, Report III GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Grabiński, J.	2020	Badanie skuteczności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 01/20, Report I GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Grabiński, J.	2020	Badanie skuteczności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 01/20, Report II GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Grabiński, J.	2020	Badanie skuteczności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 01/20, Report III GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo

3.2.3	Grabiński, J.	2020	Badanie skuteczności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 01/20, Report IV GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Krawczuk, M.	2019	Field study to evaluate the efficacy of Mezot 100 SC when applied post emergence in maize for the control of weeds, Poland 2019. SGS Poland Sp. z o.o. SGS/2019/047/PL01 GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Krawczuk, M.	2019	Field study to evaluate the efficacy of Mezot 100 SC when applied post emergence in maize for the control of weeds, Poland 2019. SGS Poland Sp. z o.o. SGS/2019/047/PL02 GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Krawczuk, M.	2019	Field study to evaluate the efficacy of Mezot 100 SC when applied post emergence in maize for the control of weeds, Poland 2019. SGS Poland Sp. z o.o. SGS/2019/047/PL03 GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Krawczuk, M.	2019	Field study to evaluate the efficacy of Mezot 100 SC when applied post emergence in maize for the control of weeds, Poland 2019. SGS Poland Sp. z o.o. SGS/2019/047/PL04 GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Krawczuk, M.	2019	Field study to evaluate the efficacy of Mezot 100 SC when applied post emergence in maize for the control of weeds, Poland 2019. SGS Poland Sp. z o.o. SGS/2019/047/PL05 GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Grabiński, J.	2019	Badanie selektywności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 02/2019, Report I GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo

3.2.3	Grabiński, J.	2019	Badanie selektywności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 02/2019, Report II GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Grabiński, J.	2020	Badanie selektywności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 01/2020, Report I GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Grabiński, J.	2020	Badanie selektywności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 01/2020, Report II GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Grabiński, J.	2020	Badanie selektywności herbicydu Mezot 100 SC w uprawie kukurydzy. IUNG Puławy NUZ 01/2020, Report III GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Krawczuk, M.	2019	Field study to evaluate the selectivity of Mezot 100 SC when applied post emergence in maize, Poland 2019. SGS Poland Sp. z o.o. SGS/2019/048/PL01 GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Krawczuk, M.	2019	Field study to evaluate the selectivity of Mezot 100 SC when applied post emergence in maize, Poland 2019. SGS Poland Sp. z o.o. SGS/2019/048/PL02 GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
3.2.3	Krawczuk, M.	2019	Field study to evaluate the selectivity of Mezot 100 SC when applied post emergence in maize, Poland 2019. SGS Poland Sp. z o.o. SGS/2019/048/PL03 GEP/Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo

KCP 2.1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.3.1	Paulina Flasińska, MSc.	2019	Determination of flash point and auto-ignition temperature. Institute of Industrial Organic Chemistry; BC-16/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.3.3	Paulina Flasińska, MSc.	2019	Determination of flash point and auto-ignition temperature. Institute of Industrial Organic Chemistry; BC-16/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.4.1 /01	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.4.1 /02	Inga Sowik, MSc.	2022	MEZOT 100 SC Determination of physicochemical properties. Institute of Industrial Organic Chemistry; BA-03/22; Warsaw; 2022 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.4.2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo

KCP 2.5.1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.5.2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.6.1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.7.1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.7.3	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.7.4	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19;	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo

			Warsaw; 2019 GLP Unpublished				
KCP 2.7.5	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.7.5 /01	Enzo Arévalo, Ph.D.	2021	Part II: Determination of physicochemical properties of the preparation after one year of storage. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.7.5 /02	Enzo Arévalo, Ph.D.	2021	Part III: Determination of physicochemical properties of the preparation after 2 years of storage. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2021 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.8.2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.8.3 .1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.8.3	Enzo Arévalo,	2019	Part I: Determination of physicochemical properties of the initial	N	Y	Data/study report never	Elvita Sp.z o.o

.2	Ph.D.		preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished			submitted before to Poland	Różewo
KCP 2.8.5 .1.1	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.8.5 .1.2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.8.7 .2	Enzo Arévalo, Ph.D.	2019	Part I: Determination of physicochemical properties of the initial preparation, ~~and~~ after accelerated storage and after storage at 0 ˚C. Institute of Industrial Organic Chemistry; BF-21/19; Warsaw; 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 2.11	Grażyna Oleksa, MSc	2022	Mezot 100 SC Cleaning of equipment. Institute of Industrial Organic Chemistry; BA-22/22; Warsaw; 2022 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 5.1.1	Wołoszynowska M., Chałas A.	2019	MEZOT 100 SC Method validation for determination of the active substance and two relevant impurities content in the formulation. Institute of Industrial Organic Chemistry, Warszawa GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 5.1.2	Niewelt S.	2019	Residues of Mesotrione on maize plants after spray application of	N	Y	Data/study report never	Elvita Sp.z o.o

			Mezot 100 SC in early growth stages of maize in Poland – magnitude of residues and time course of residue decline – 2019. Analytical Phase. Report No.: DPL/122/2019 (19SGS10) SGS Polska Sp. z o.o., Warszawa GLP Unpublished			submitted before to Poland	Różewo
KCP 7.1.4	Krakowian D.	2019	Mezot 100 SC: In Vitro Skin Corrosion: Reconstructed Human Epidermis Test Method Study code: SCT-2/19 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP; Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 7.1.5/01	Gruszka K.	2019	Mezot 100 SC: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage Study code: ICE-5/19 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP; Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 7.1.5/02	Krakowian D.	2019	Mezot 100 SC: Short time exposure in vitro test method for identifying I) chemicals inducing serious eye damage and II) chemicals not requiring classification for eye irritation or serious eye damage Study code: STE-4/19 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP; Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 7.1.5/03	Gruszka K.	2020	Mezot 100 SC: Acute Eye Irritation/Corrosion Study on Rabbits Study code: ODR-1/20 Institute of Industrial Organic Chemistry, Branch Pszczyna GLP; Unpublished	Y	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 9.2.4.1	Janus, K.	2020	PECgw calculation for Mezot 100 SC. Report No.: 1/2020 non GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 9.2.5	Janus, K.	2020	PECsw calculation for Mezot 100 SC. Report No.: 2/2020 non GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo

KCP 10.1.2 /01	~~Karol~~ Łukaszewski. K.	2019	Residues of Mesotrione on maize plants after spray application of Mesotrione 100 SC in early growth stages of maize in Poland – magnitude of residues and time course of residue decline – 2019 19SGS10 SGS Polska GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.1.2/02	I. Katzschner	2018	Generic monitoring of European hares in Central Europe to determine the proportion of time spent foraging in early maize. RIFCON GmbH R1740065 GLP/No Published	~~Y~~	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.2.1	[redacted]	2019	MEZOT 100 SC Rainbow trout, Acute toxicity test [redacted]	Y	Y	Data/study report never submitted before to Poland	[redacted]
KCP 10.2.1	~~Ewa~~ Nierzędska, E.	2019	MEZOT 100 SC Daphnia magna, Acute Immobilization Test IPO Pszczyna W/33/19 GLP/No Published	Y	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.2.1	~~Ewa~~ Nierzędska, E.	2019	MEZOT 100 SC Pseudokirchneriella subcapitata SAG 61.81 Growth Inhibition Test IPO Pszczyna W/34/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.3.1.1.1	~~Ewa~~ Nierzędska, E.	2019	MEZOT 100 SC Lemna gibba CPCC 310 Growth Inhibition Test IPO Pszczyna W/35/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.3.1.1.2/ 01	~~Mateusz~~ Grzesica, M.	2019	Mezot 100 SC Honeybees (Apis mellifera L.), Acute Oral Toxicity Test IPO Pszczyna B/34/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.3.1.1.2/ 02	~~Mateusz~~ Grzesica, M.	2019	MEZOT 100 SC Honeybees (Apis mellifera L.), Acute Contact Toxicity Test IPO Pszczyna B/35/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP	~~Elżbieta~~	2019	Mezot 100 SC Honeybees (Apis mellifera L.), Larval Toxicity Test,	N	Y	Data/study report never	Elvita Sp.z o.o

10.3.1.3	Kulec-Płoszczyca, E.		Single Exposure IPO Pszczyna B/31/19 GLP/No Published			submitted before to Poland	Różewo
KCP 10.3.1.2	~~Elżbieta~~ Kulec-Płoszczyca, E.	2019	Mezot 100 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test IPO Pszczyna B/33/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.4.1.1	~~Paweł~~ Pieczka, P.	2020	MEZOT 100 SC Earthworm Reproduction Test IPO Pszczyna G/64/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.5	~~Paweł~~ Pieczka, P.	2020	MEZOT 100 SC Soil Microorganisms: Nitrogen Transformation Test IPO Pszczyna G/65/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.3.2	~~Monika~~ Stalmach, M.	2019	A laboratory test for evaluating the effects of Mezot 100 SC on the predatory mite, *Typhlodromus pyri*. IPO Pszczyna B/29/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.3.2	~~Monika~~ Stalmach, M.	2019	A laboratory test for evaluating the effects of Mezot 100 SC on the parasitic wasp, *Aphidius rhopalosiphi*. IPO Pszczyna B/30/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.6	~~Magdalena~~ Wołany, M.	2020	MEZOT 100 SC Terrestial Plant Test: Seedling Emergence and Seedling Growth Test. IPO Pszczyna G/62/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo
KCP 10.6	~~Magdalena~~ Wołany, M.	2020	MEZOT 100 SC Terrestrial Plant Test: Vegetative Vigour Test. IPO Pszczyna G/63/19 GLP/No Published	N	Y	Data/study report never submitted before to Poland	Elvita Sp.z o.o Różewo