FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

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: 08/2023; 12/2023

Version history

When	What
02.02.2023	Point 9.3.2.2 – Completion of data and information.
10.07.2023	Point 9.3.2.2 – Completion of data and information.
10.07.2023	Appendix 2, point 2.2.1. Amendment – study W/35/10
10.07.2023	Appendix 2, point 2.6. Amendment – study G/62/19 and G/63/19
08.2023	ZRMs evaluated dRR submitted by Applicant
12.2023	The final Registration Report

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9 Ecotoxicology (KCP 10)

This document reviews the ecotoxicology for the product Mezot 100 SC containing Mesotrione as active substance which was included into Annex I of Directive 91/414 (current legislation – regulation 540/2011) by Directive 2003/68/EC (July, 11th 2003) and renewed by Regulation (EU) 2017/725 of April, 24th 2017.
A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

Where appropriate this document refers to the conclusions of the EU review of Mesotrione. This will be where:

- the protection of operators,
- the protection of groundwater in vulnerable regions,
- the protection of mammals, aquatic and non-target plants..

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II data must only be included if they are considered essential for the evaluation and in this case a full study summary must be provided.

Mezot 100 SC as formulation has not been previously evaluated in Poland according to Uniform Principles.

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 reference to where such information can be found.

The Annex I Directive 2003/68/EC (July, 11th 2003) and Regulation (EU) 2017/725 of April, 24th 2017 provide specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the Mesotrione and in particular Appendices thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 March 2017 (SANTE/11654/2016) shall be taken into account.

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	**Member state(s)**	**Crop and/ or situa-tion** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expres-sion, dose range (min-max)	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
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 pur-pureum, Tripleurospermum ino-dorum, Fallopia convolvulus, Sinapis arvensis, Solanum nigrum, Stellaria media, Thlaspi arvense, Viola arven-sis.*	Foliar spraying; small drops	BBCH 12-18	1	-	a) 1,5 b) 1,5	Mesotrione - 150	200-300	-	Herbicide for use with field sprayers	A	C	R	A	A	A	R

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

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

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where 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) Re marks may include: Extent of use/economic importance/restrictions

9.1.1 Overall conclusions

An estimation of risk indicate acceptable risk for each organisms of each range of assessed issues, taking into consideration adequate mitigation measures.

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

An estimation of risk indicate low risk for birds and mammals of each range of assessed issues.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

An estimation of risk indicate accepted risk for aquatic organisms, taking into consideration adequate mitigation measures.

9.1.1.3 Effects on bees (KCP 10.3.1)

An estimation of risk indicate low risk for bees of each range of assessed issues.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

An estimation of risk indicate accepted risk for arthropods other than bees.

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

An estimation of risk indicate accepted risk for microbial activity.

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

An estimation of risk indicate accepted risk.

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No studies submitted.

9.1.2 Grouping of intended uses for risk assessment

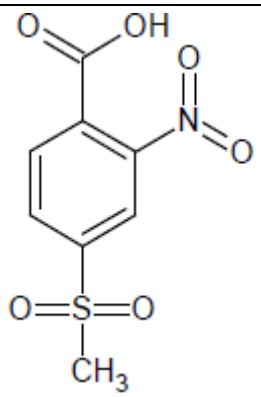
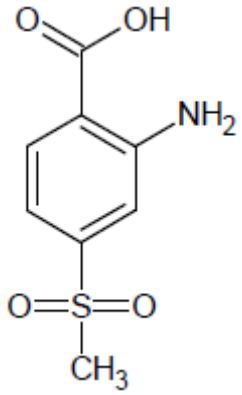
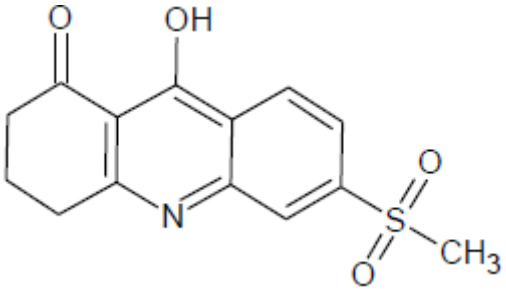
Mezot 100 SC is intended to use in maize.

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a

metabolite-specific risk assessment in the context of the evaluation of Mezot 100 SC is indicated in the table.

Table 9.1-2 Metabolites of Mesotrione

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
MNBA; 4-(methylsulfonyl)-2-nitrobenzoic acid	245		~~57,2 %~~ ~~100 %~~ ~~7,9 %~~ Soil: 57.2 % Water: 7.9% Sediment: <1% Water/sediment: 7.9%	Soil Ground water Surface water
AMBA; 2-amino-4-(methylsulfonyl)benzoic acid	215		~~9,7 %~~ ~~25 %~~ ~~24,6 %~~ Soil: 9.7% Water: 15.8% Sediment: 8.8% Water/sediment: 24.6%	Soil Ground water Surface water
SYN 546974; 9-hydroxy-6-(methylsulfonyl)-3,4-dihydroacridin-1(2H)-one	291		- - ~~33,0 %~~ Soil: <1 x 10^{-10}% Water: 9.4% Sediment: 25.6% Water/sediment: 33%	Soil Ground water Surface water

zRMS comments

Information relating to mesotrione metabolites are in line with EU agreed endpoints as reported in EFSA Journal 2016;14(3):4419 and have been considered in the exposure assessment presented in this report.
All comments and conclusions of the zRMS are presented in grey.
Minor changes are introduced directly in the text and highlighted in grey.
Not agreed or not relevant information are struck through and shaded for transparency.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Mesotrione. Full details of these studies are provided in the respective EU DAR and related documents.
Effects on birds of formulation were not evaluated as part of the EU assessment of Mesotrione.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Time scale	Results [mg/kg bw/day]	Reference
Bobwhite quail	Mesotrione	Acute	LD_{50} > 2000 mg/kg bw/d, single dose	EFSA Conclusion
Mallard duck / Bobwhite quail	Mesotrione	Short-term	LC_{50} > 5200 ppm food	EFSA Conclusion
Mallard duck	Mesotrione	Long-tem	NOEL = 120 mg a.s./kg diet = 20.6 mg a.s./kg bw/d	EFSA Conclusion

zRMS comment: zRMS confirms that the reported toxicity data in table 9.2-1 are in accordance with the EU agreed end-points and will be used for risk assessment.

9.2.1.1 Justification for new endpoints

Studies with the formulation were not performed.
Please refer to Conclusion on the peer review of the pesticide risk assessment of the active substance Mesotrione (EFSA Journal 2016;14(3):4419.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.2-2-1: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of Mezot 100 SC in Maize.

Intended use		**Maize**			
Active substance/product		Mesotrione			
Application rate (kg/ha)		1 × 0,150			
Acute toxicity (mg/kg bw)		2000			
TER criterion		10			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Maize	Small omnivorous bird	158,8	1,0	23,82	83,96
Reprod. toxicity (mg/kg bw/d)		20,6			
TER criterion		5			
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Rape	Small omnivorous bird	64,8	1,0 x 0,53	5,15	**4**

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.

9.2.2.2 Higher-tier risk assessment

Table 9.2-3-2: Higher-tier assessment of the long-term/reproductive risk for birds due to the use of Mezot 100 SC in Maize.

Intended use	**Maize**
Active substance/product	Mesotrione
Application rate (kg/ha)	1 × 0,150
Reprod. toxicity (mg/kg bw/d)	20,6

TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize BBCH 10-19	Small insectivorous/worm feeding species “thrush”	5.7	1 x 0,53	0.45	45,8
Maize BBCH 10-29	Small omnivorous bird “lark”	10.9		0.87	23,7
Maize BBCH 10-29	Medium herbivorous/ granivorous “pigeon”	22.7		1.80	11,4
Maize BBCH 10-19	Small insectivorous bird “wagtail”	11.3		0.9	22,9
Maize BBCH 10-29	Medium granivorous bird “gamebird”	3		0.24	85,8

Risk acceptable.

zRMS comment: Agreed.

9.2.2.3 Drinking water exposure

Leaf scenario

In this scenario according to EFSA Guidance Document birds are taking water that is collected in leaf whorls after application of pesticide to crop and subsequent rainfall or irrigation.

Leaf scenario not occurred after using Mezot 100 SC.

There's no risk from leafy scenario.

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 < 500 L/kg, Mesotrione belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

Effective application rate (g/ha) = 150		Trigger Value:
Acute toxicity (mg/kg bw) = 2000	quotient = 0,075	50
Reprod. toxicity (mg/kg bw/d) = 20,6	quotient = 7,3	50

There's no risk from puddle scenario.

zRMS comment: Agreed.

9.2.2.4 Effects of secondary poisoning

According to EFSA Guidance Document on Risk Assessment for Birds and Mammals, 2009, substances with a log POW lower than 3 haven't potential for bioaccumulation. Mesotrione has a log Pow < 3, and not indicating a potential risk of secondary poisoning, therefore a risk assessment is not required.

zRMS comment: Agreed.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

An estimation of risk indicate low risk for birds of each range of assessed issues.

zRMS comment: The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438). The presented above birds risk assessment is agreed by the zRMS. All TER values exceed the relevant triggers indicating that **MEZOT 100 SC** does not pose an unacceptable risk to birds following applications according to recommended use pattern. On the basis of performed calculations, acceptable acute and long-term risk to birds may be concluded from proposed uses of **MEZOT 100 SC.**

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with formulation Mezot 100 SC and active substance Mesotrione. Full details of these studies are provided in the respective EU DAR and related documents as well as in Section 6 (Mammalian Toxicology) of this report (new studies).

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Time scale	Results [mg/kg bw/day	Reference
Rat	Mesotrione	Acute	> 5000	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Rat	Mesotrione	Long-term	0,3 NOEL=1.2 mg a.s./kg bw/d*	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Rat	MNBA	Acute	> 5000	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Rat	AMBA	Acute	> 5000	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419

*For details, please see the consideration below.

9.3.1.1 Justification for new endpoints

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active substance Mesotrione (EFSA Journal 2016;14(3):4419).

zRMS comment: zRMS confirms that the reported toxicity data in table 9.3-1 are in accordance with the EU agreed end-points and will be used for risk assessment.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

Table 9.3-2-1: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Mezot 100 SC in Maize.

Intended use	Maize				
Active substance/product	Mesotrione				
Application rate (kg/ha)	1 × 0,150				
Acute toxicity (mg/kg bw)	5000				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Maize	Small herbivorous mammal	136,4	1,0	20,46	244,4
Reprod. toxicity (mg/kg bw/d)	0,3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize	Small herbivorous mammal	72,3	1,0 x 0,53	5,75	**0,052**

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.

zRMS comment: 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.

Table 9.3-3-1: First-tier assessment of the acute risk for mammals due to the use of Mezot 100 SC in Maize – data for metabolites.

Intended use	Maize	
Active substance/product	MNBA	AMBA
Application rate (kg/ha)	1 × 0,150 *	1 × 0,150 *
Acute toxicity (mg/kg bw)	5000	
TER criterion	10	

Compound	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
MNBA	Small herbivorous mammal	136,4	1,0	20,46	244,4
AMBA	Small herbivorous mammal	136,4	1,0	20,46	244,4

* - worst case scenario – 100 % formation fraction
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

zRMS comment: 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.

9.3.2.2 Higher-tier risk assessment

Further risk assessment must be done for long-term risk for mammals due to low value of TERlt.

Table 9.3-4: 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)		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 × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize (BBCH 10-19)	Small insectivorous mammal "shrew"	4.2	1,0 x 0,53	0,33	**0,91**
Maize (BBCH 10-29)	Small herbivorous mammal "vole"	72.3	1,0 x 0,53	5,75	**0,05**
Maize (BBCH 10-29)	Small omnivorous mammal "mouse"	7.8	1,0 x 0,53	0,62	**0,48**

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comment: 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 DT_{50} for mesotrione on maize could be determined from the residue decline study, therefore the default 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 perfomed. 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

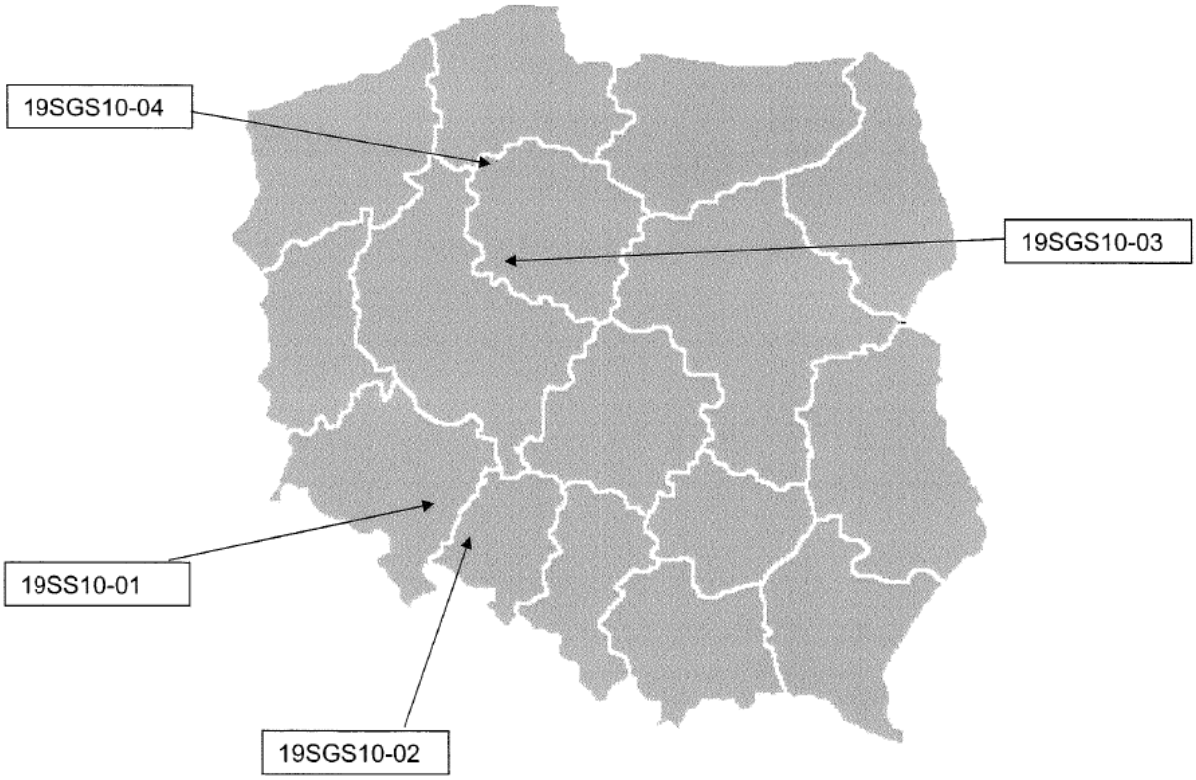
Test system:

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

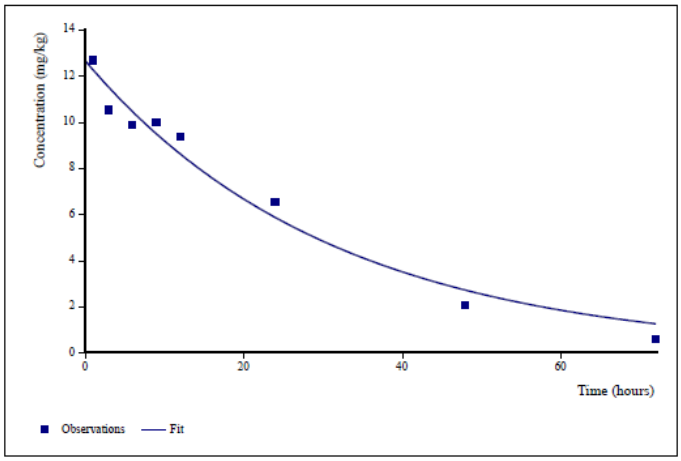


Figure 1.1. Observations and Fitted Model: SFO

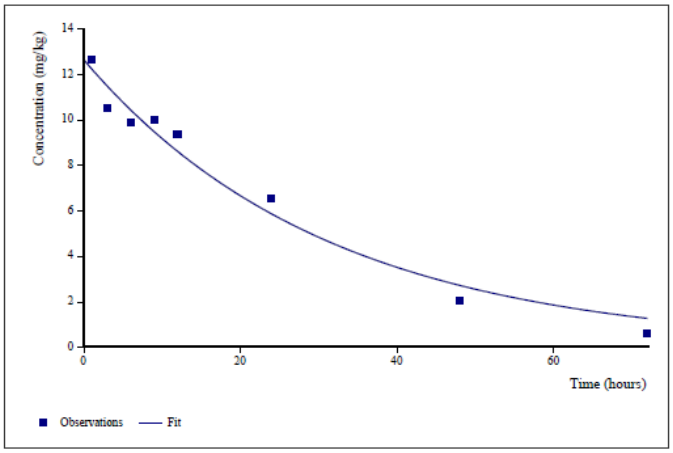


Figure 1.5. Observations and Fitted Model: DFOP

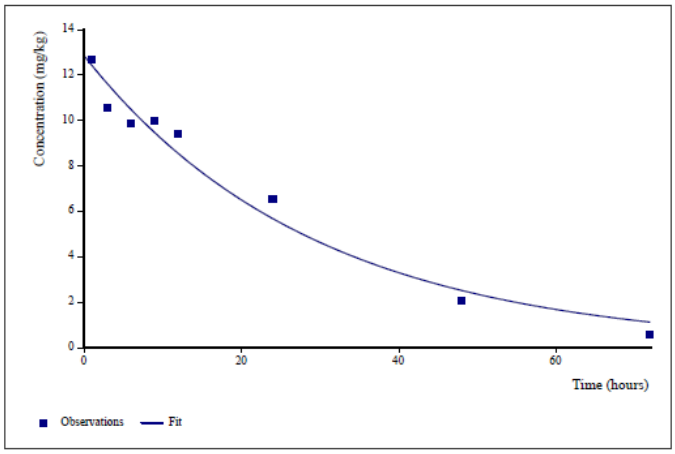


Figure 1.9. Observations and Fitted Model: FOMC

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

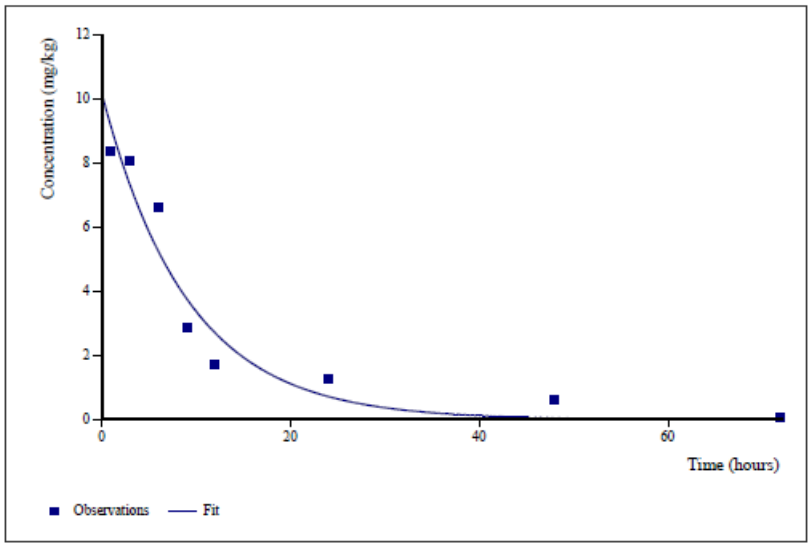


Figure 2.1. Observations and Fitted Model: SFO

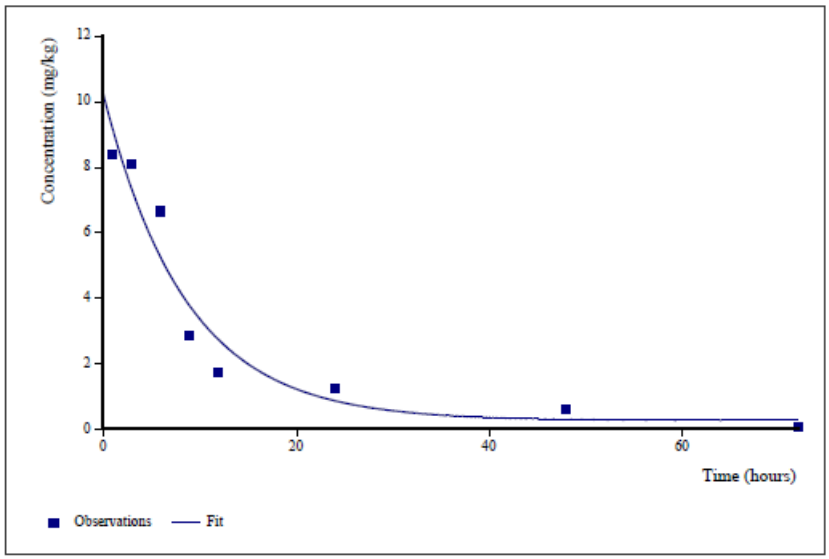


Figure 2.5. Observations and Fitted Model: DFOP

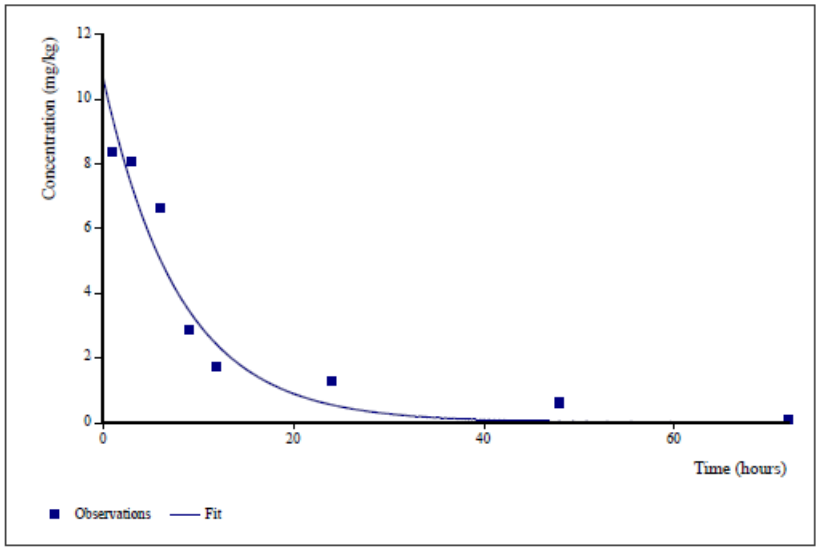


Figure 2.9. Observations and Fitted Model: FOMC

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

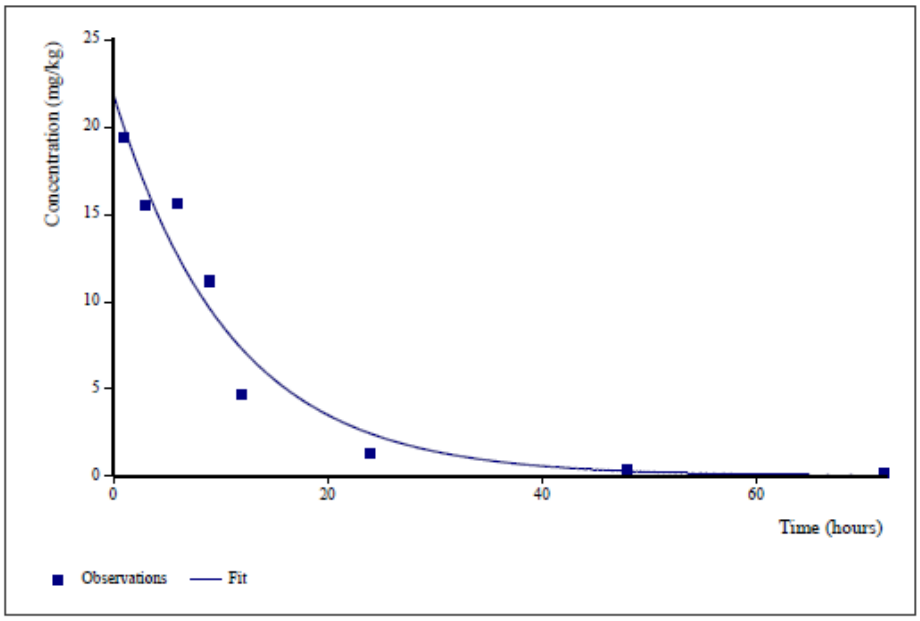


Figure 3.1. Observations and Fitted Model: SFO

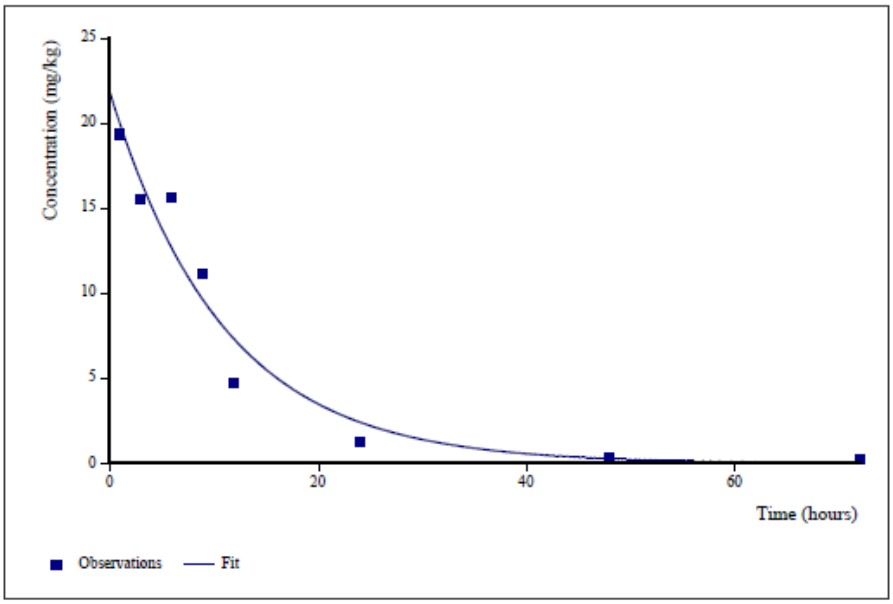


Figure 3.5. Observations and Fitted Model: DFOP

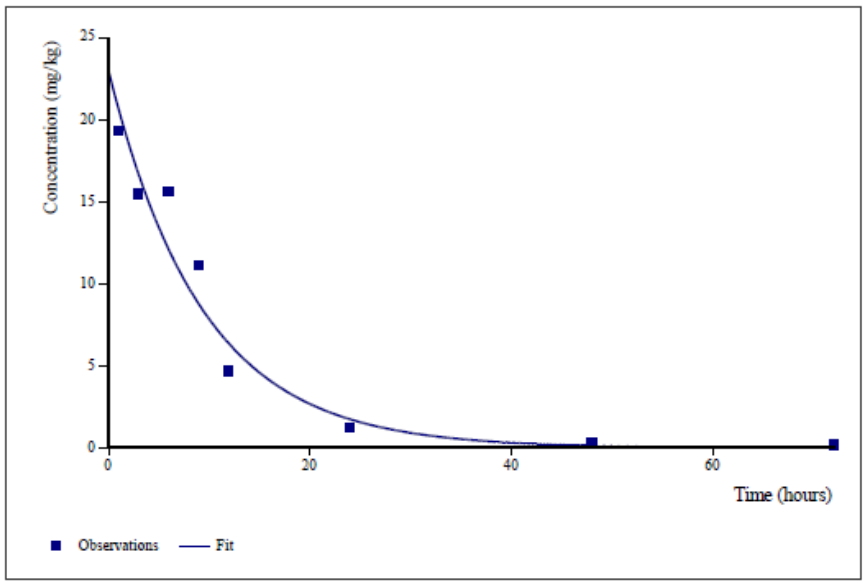


Figure 3.9. Observations and Fitted Model: FOMC

Conclusion: All 3 models have a $Ch^{\wedge 2}$ 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

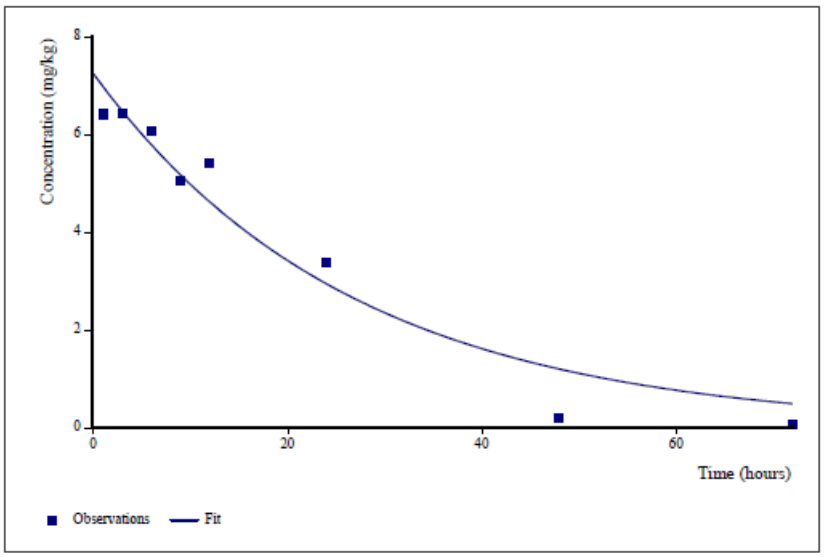


Figure 4.1. Observations and Fitted Model: SFO

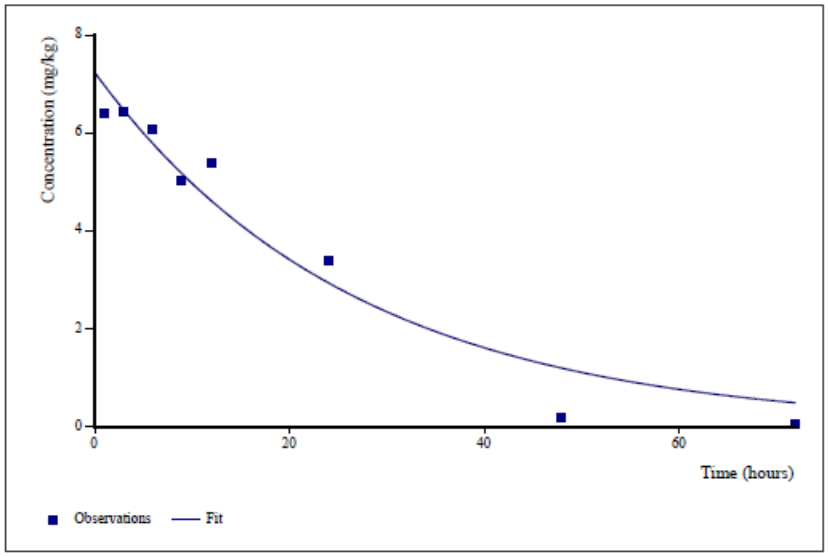


Figure 4.5. Observations and Fitted Model: DFOP

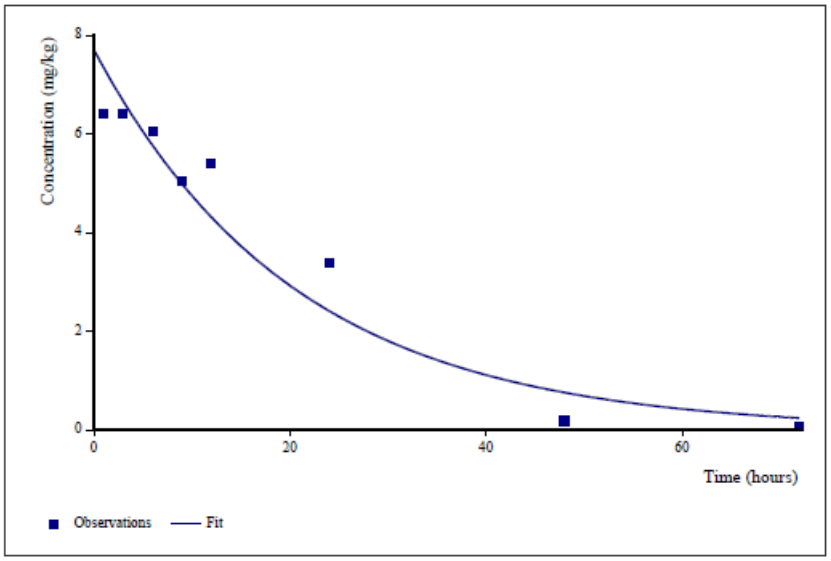


Figure 4.9. Observations and Fitted Model: FOMC

Conclusion: All 3 models have $Ch^{\wedge 2}$ error below 15% and the lowest result was found for the SFO model, i.e. $Ch^{\wedge 2}$ 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.

Comments of zRMS:	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.

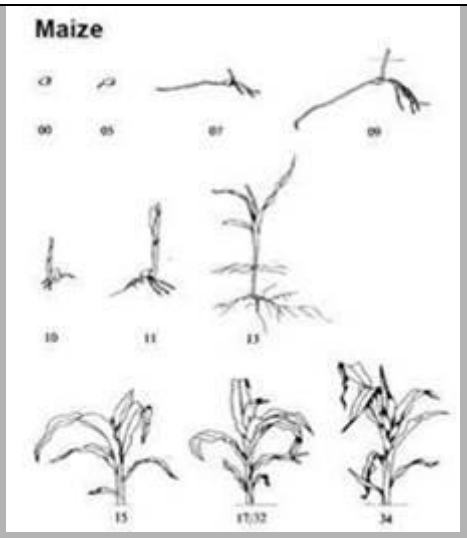
Trial 19SGS10-01 located in Piskorzówek, postal code: 55-216 (GPS coordinates N 50°54'14", E 17°8'51,4) according to topography map, was located 143,1 m above sea level. Trial 19SGS10-02 located in Grodków, postal code: 49-200 (GPS coordinates N 50°41'3,5", E 17°21'5,4") was located 176 m above sea level. 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.

Refinement of DT_{50} should be considered at MSs level.

Table 9.3-5: 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 spe-

cific 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.

The focal species in maize should be considered by MSs level.

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
Hun-gary	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 comment: zRMS agrees with the refined PT value (PT = 0.139) for wood mouse and PT value (PT = 0.62) for brown hare.

The refinement PT value for wood mouse and brown hare should be considered by MSs level.

~~**Table 9.3-6: 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**	**PD/diet type**	**FIR/bw**	**RUD**	**MAF$_m$ × f$_{TWA}$**	**PT**	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Maize (BBCH 10-29)	Small mammal "wood mouse"	0,25 (Plant material – Maize)	0,27	54,2	0,038	0,139	0,011	-
		0,25 (Ground Arthro-pods)		3,5[a]			0,0002	
		0,50 (Weed seeds)		40,2			0,004	
						Total:	0,015	20

[a] According to Appendix A from EFSA (2009), RUD values for arthropods with interception are relevant to maize at BBCH 10-29

Table 9.3-7: 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**	**PD/diet type**	**FIR/bw**	**RUD**	**MAF$_m$ × f$_{TWA}$**	**PT**	**DDD$_m$ (mg/kg bw/d)**	**TER$_{lt}$**
Maize (BBCH 10-29)	Brown hare (*Lepus europaeus*)	0,84 (Maize shoots)	0,32	54,2	0,038	0,66	0,055	-
		0,16 (Dicot weeds)		28,7			0,005	
						Total:	0,060	5

zRMS comment: The refined PD value (0.84 – maize shoots and 0.16 – dicot weeds) for Brown hare was reject by zRMS.

The refinement PD value for brown hare should be considered by MSs level.

zRMS comment:

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 is required as TER_{LT} is below the trigger of 5 (TER_{lt} = 3.0).

The refinement risk assessment for mammals should be considered by MSs level.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf.* Appendix K of EFSA/2009/1438).

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 < 500 L/kg, Mesotrione belongs to the group of less sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

Effective application rate (g/ha) = 150		Trigger value:
Acute toxicity (mg/kg bw) = 5000	quotient = 0,03	50
Reprod. toxicity (mg/kg bw/d) = 0,3	quotient = 500	50

Trigger value of long-term toxicity endpoint is above 50. This indicates the need of a refinement risk assessment.

Reproductive risk for mammals from exposure via drinking water from puddles following application of Mezot 100 SC:

Substance	AR/10 (mg/m^2)	K_{oc}	PEC_{puddle} (mg a.s./L)	DWR (L/kg bw/day)	DDD (mg a.s./kg bw/day)	Reproductive endpoint (mg a.s./kg bw/day)	TER_{LT}	Trigger
Mesotrione	15	109	0.0817	0.24	0.0196	0,3	15,3	5

Where:

$$PEC_{puddle} = \frac{AR/10}{1000\ (w + Koc * s)}$$

AR = application rate (g/ha); divisor of 10 to achieve rate in mg/m^2
w = 0.02 (pore water term; volume)
s = 0.0015 (soil term: volume, density, organic carbon content

The drinking water rate (DWR) for small granivorous mammal wood mouse (generic focal species) was calculated to be 0.24 L/kg bw/d using the following equation given by the EFSA Guidance Document:

$Log_{10}(WF) = - 0.110 + 0.734 \times log_{10}(bw)$ for non-desert species

Body weight = 21.7 g
WF = 7.4 mL/d;
DWR = WF – (food water + metabolic water) = 5.1 mL/d, equivalent to 0.24 L/kg bw/d for wood mouse

The daily dietary dose (DDD) is then calculated as follows: DDD = PEC_{puddle} x DWR

The TER_{LT} for exposure of mammals via drinking water following application of Mezot 100 SC in maize exceeds the trigger value of 5, so the risk for mammals is acceptable.

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 sorptive 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	miaze
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. **Refinement chronic risk to mammals from drinking water from puddles is required. Chronic risk to mammals from drinking water from puddles should be considered by MSs level.**

9.3.2.3 Effects of secondary poisoning

According to EFSA Guidance Document on Risk Assessment for Birds and Mammals, 2009, substances with a log POW lower than 3 haven't potential for bioaccumulation. Mesotrione has a log Pow < 3, and not indicating a potential risk of secondary poisoning, therefore a risk assessment is not required.

zRMS comment: The evaluation of the risk of secondary poisoning for earthworm-eating mammals and fish-eating-mammals for mesotrione is not triggered due to log Pow being <3.

9.3.2.4 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

An estimation of risk indicate low risk for mammals of each range of assessed issues.

zRMS comment: In the screening step the TER_A values for mesotrione exceeds the trigger value (10), indicating that **Mezot 100 SC** presents an acceptable acute risk to mammals.

The TER_{LT} values from the tier 1 reproductive risk assessment are below the trigger of 5 for the use on maize, indicating that **Mezot 100 SC** presents an unacceptable long-term risk to mammals.

A higher tier long-term risk assessment based on the following refinement parameters: foliage residue dissipation (DT_{50}) and ecological data on PT values as well as ecological toxicity endpoints for mammals should be considered by MSs level..

The high long-term drinking water risk was identified for dose rate 150 g a.s./ha using the Koc value for pH 7.8 (14 L/kg). 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. However, NOEAL of 1.2 mg a.s./kg bw should be considered at MSs level.

Refinement long-term risk assessment should be considered at MS level.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

There is no additional data.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Mezot 100 SC, Mesotrione and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document (new studies).

Effects on aquatic organisms of Mezot 100 SC were not evaluated as part of the EU assessment of Mesotrione. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – active substance (Mesotrione) / and relevant metabolites

Species	Substance	Exposure System	Results [mg/L]	Reference
Oncorhynchus mykiss *Lepomis macrochirus*	Mesotrione	96 h	LC_{50} > 120 (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Pimephales promelas	Mesotrione	36 d	NOEC = 12,5 (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Oncorhynchus mykiss	MNBA	96 h	LC_{50} > 120 (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Oncorhynchus mykiss	AMBA	96 h	LC_{50} > 150 (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Dapnia magna	Mesotrione	48 h	EC_{50} > 622 (mm)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Dapnia magna	Mesotrione	21 d	NOEC = 180 (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Dapnia magna	MNBA	48 h	EC_{50} = 130 (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Dapnia magna	AMBA	48 h	EC_{50} = 160 (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
~~*Pseudokirchneriella subcapitata*~~ *Raphidocelis subcapitata*	Mesotrione	120 h	E_bC_{50}= 3.5 mg a.s./L (nom) E_rC_{50}= 13 mg a.s./L (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
~~*Pseudokirchneriella subcapitata*~~ *Raphidocelis subcapitata*	MNBA	72 h	EC_{50} = 38 (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
~~*Pseudokirchneriella subcapitata*~~ *Raphidocelis subcapitata*	AMBA	72 h	E_bC_{50} = 9,4 (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Lemna gibba	Mesotrione	14 d	E_bC_{50} (for frond no.)= 0.022 mg a.s./L (nom) E_bC_{50} (for dry weight)= 0.0077 mg a.s./L (nom)	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Lemna gibba	MNBA	7 d	E_rC_{50}/ E_yC_{50} (for both)>97 mg a.s./L mm	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419
Lemna gibba	AMBA	7 d	E_rC_{50}/ E_yC_{50} (for	~~EFSA Conclusion~~

Species	Substance	Exposure System	Results [mg/L]	Reference
			both)>90 mg a.s./L mm	EFSA Journal 2016;14(3):4419
Lemna gibba	SYN 546974	7 d	E_rC_{50} (for both)>95 mg a.s./L mm E_rC_{50} (for fronf no.) =93 mg a.s./L mm	~~EFSA Conclusion~~ EFSA Journal 2016;14(3):4419

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – formulation Mezot 100 SC.

Species	Substance	Exposure System	Results [mg/L]	Reference
Rainbow trout	Mezot 100 SC	96 h	LC_{50} = 6.27 mg formulation/L LC_{50} = 0.58 mg s.a./L*	[redacted]
Daphnia magna	Mezot 100 SC	48 h	EC_{50} = 16.91 mg formulation/L LC_{50} = 1.56 mg s.a./L*	IPO Pszczyna Report W/33/19
~~*Pseudokirchneriella subcapitata*~~ *Raphidocelis subcapitata*	Mezot 100 SC	72 h	E_rC_{50} = 21.11 mg formulation/L E_yC_{50} = 1.95 mg s.a./L	IPO Pszczyna Report W/34/19
Lemna gibba	Mezot 100 SC	7 d	EC_{50} = 0.572 ng formulation/L EC_{50} = 0.053 mg s.a./L	IPO Pszczyna Report W/35/19
* based on density of formulation – Mezot 100 SC = 1.084 g/ml (dRR Secion 1)				

9.5.1.1 Justification for new endpoints

Please refer to Conclusion on the peer review of the pesticide risk assessment of the active substance Mesotrione (EFSA Journal 2016;14(3):4419).

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).
The relevant global maximum FOCUS Step 1, 2, 3 and 4 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

In the following tables, the ratios between predicted environmental concentrations in surface water bodies

(PECSW, PECSED) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Table 9.5-3-1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mesotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of Mezot 100 SC in Maize.

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic Plants**
Test species		***Oncorhynchus mykiss***	***Pimephales promelas***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}	EC_{50}
(µg/L)		120 000	12 500	622 000	180 000	3 500	7,7
AF		100	10	100	10	10	10
RAC (µg/L)		1200	1250	6220	18000	350	0,77
FOCUS Scenario	**PEC $_{sw\text{-}max}$ (µg/L) *)**	**PEC/RAC**					
Step 1 (pH 7.9)							
	50.25	0.0419	0.0402	0.0081	0.0028	0.1436	**65.2597**
Step 2							
N-Europe (pH 6.5)	6.56	0.0055	0.0052	0.0011	0.0004	0.0187	**8.5195**
S-Europe (pH 6.5)	12.33	0.0103	0.0099	0.0020	0.0007	0.0352	**16.0130**
Step 3							
D3/ditch (pH 6.5)	0.7865	0.0007	0.0006	0.0001	0.0000	0.0022	**1.0214**
D4/pond (pH 5.1)	0.04633	0.0000	0.0000	0.0000	0.0000	0.0001	0.0602
D4/stream (pH 5.1)	0.6514	0.0005	0.0005	0.0001	0.0000	0.0019	0.8460
R1/pond (pH 5.1)	0.05399	0.0000	0.0000	0.0000	0.0000	0.0002	0.0701
R1/stream (pH 6.5)	2.390	0.0020	0.0019	0.0004	0.0001	0.0068	**3.1039**
***)** - PECsw-max depend on worst case scenario in regards to pH							

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-3-2: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolites of Mesotrione for each organism group based on FOCUS Steps 1, 2 calculations for the use of Mezot 100 SC in Maize

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Fish acute	Inverteb. acute	Algae	Aquatic Plants
MNBA			**LC50 = 120 (mg/L) RAC = 1200**	**LC50 = 130 (mg/L) RAC = 1300**	**LC50 = 38 (mg/L) RAC = 3800**	**LC50 = 97 (mg/L) RAC = 9700**
Step 1	---	23,48	0.0196	0.0181	0.0062	0.0024
Step 2						
North	March-May	1,89	0.0016	0.0015	0.0005	0.0002
South	March-May	3,71	0.0031	0.0029	0.0010	0.0004
SYN 546974			-	-	-	**LC50 = 93 (mg/L) RAC = 9300**
Step 1	---	0,77	-	-	-	0.0001
Step 2						
North	March-May	0,39	-	-	-	0.0000
South	March-May	0,39	-	-	-	0.0000
AMBA (Linear; pH 7.9) - worst case scenario in regards to pH			**LC50 = 150 (mg/L) RAC = 1500**	**LC50 = 160 (mg/L) RAC = 1600**	**LC50 = 94 (mg/L) RAC = 940**	**LC50 = 90 (mg/L) RAC = 9000**
Step 1	---	10,83	0.0090	0.0083	0.0029	0.0011
Step 2						
North	March-May	1,62	0.0014	0.0012	0.0004	0.0002
South	March-May	3,02	0.0025	0.0023	0.0008	0.0003

For the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for some scenarios (RAC=0,77 µg/L). Therefore, further assessment is necessary. PEC/RAC ratios were calculated based on FOCUS Step 4 PECsw considering reduced exposure of surface water bodies.

Table 9.5-4-3: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Mesotrione based on FOCUS Step 4 calculations regarding use of Mezot 100 SC in Maize

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

9.5.3 Overall conclusions

According to mitigation measures, use of Mezot 100 SC cause accepted effect to aquatic organisms:

1. Maize – 20 m no-spray buffer zone

zRMS comment: The evaluation of the risk for aquatic organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters" (EFSA Journal 2013;11(7):3290).

The PEC_{sw} calculations for mesotrione have been approved for applications proposed in GAP. PEC_{sw} and PEC_{sed} calculations were carried out according to the FOCUS recommendations. The Applicant has been used FOCUS models: STEPS 1-2 and Step 3. $PEC_{sw/sed}$ were also carried out at Step 4 according to FOCUS L&M Guidance for 10m and 20m buffer zone.

The relevant predicted environmental concentrations in water (PEC_{sw}) for risk assessments covering the proposed use pattern are taken from Part B Section 8 (Environmental Fate). Details on PEC_{sw} calculations for mesotrione and formulation **Mezot 100 SC** are included in Section B8.

The acceptability of proposed risk mitigation measures should be taken at MSs level.

Conclusion from the risk assessment based on the active substance mesotrione:
The ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for a.s.- mesotrione based on the worst case for aquatic organisms were <1 indicating acceptable risk to aquatic organism **with applying 20 m no-spray buffer zone (the worst case scenario – R1 stream).**

Conclusion from the risk assessment based on the formulated product:

The risk assessment for the formulated product is not provided by Applicant. The risk assessment for aquatic organisms and formulation Mezot 100 SC was provided by zRMS.

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Mezot 100 SC expressed as substance active – mezotrione for each organism group based on FOCUS Steps 1, 2 and 3 calculations in Maize.

Group		**Fish acute**	**Inverteb. acute**	**Algae**	**Aquatic Plants**
Test species		***Rainbow trout***	***Daphnia magna***	***Pseudokirchneriella subcapitata***	***Lemna gibba***
Endpoint		LC_{50}	EC_{50}	E_rC_{50}	EC_{50}
(µg/L)		580	1560	1950	53
AF		100	100	10	10
RAC (µg/L)		5.80	15.60	195	5.3
FOCUS Scenario	**PEC_{sw-max} (µg/L) *)**	**PEC/RAC**			
Step 1 (pH 7.9)					
	50.25	**8.7**	**3.22**	0.25	**9.48**
Step 2					
N-Europe (pH 6.5)	6.56	**1.13**	0.42	0.03	**1.23**
S-Europe (pH 6.5)	12.33	**2.13**	0.79	0.06	**2.33**
Step 3					
D3/ditch (pH 6.5)	0.7865	0.14	-	-	0.15
D4/pond (pH 5.1)	0.04633	0.008	-	-	0.009
D4/stream (pH 5.1)	0.6514	0.11	-	-	0.12
R1/pond (pH 5.1)	0.05399	0.009	-	-	0.01
R1/stream (pH 6.5)	2.390	0.41	-	-	0.45
*) - PECsw-max depend on worst case scenario in regards to pH					

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Risk assessment for aquatic organisms and formulation Mezot 100 SC was resolved without requiring mitigation options based on FOCUS step 3.

Final risk mitigation measures should be considered at MSs level.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Mesotrione and formulation Mezot 100 SC. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
Apis mellifera	Mesotrione	Oral	LD_{50} > 11 µg/bee	EFSA Conclusion
Apis mellifera	Mesotrione	Contact	LD_{50} > 100 µg/bee	EFSA Conclusion
Apis mellifera	Mezot 100 SC	Oral	LD_{50} > 200 µg/bee	IPO Pszczyna Study code: B/34/19 OECD 213
Apis mellifera	Mezot 100 SC	Contact	LD_{50} > 200 µg/bee	IPO Pszczyna Study code: B/35/19 OECD 214
Apis mellifera	Mezot 100 SC	Chronic	LC_{50} > 667 mg/kg LDD_{50} > 11,7 µg/bee/day	IPO Pszczyna Study code: B/33/19 OECD 245
Apis mellifera (Larva)	Mezot 100 SC	Acute (72 h)	LD_{50} > 100 µg/larva	IPO Pszczyna Study code: B/31/19 OECD 237
Apis mellifera (Larva)	Mezot 100 SC	Chronic	ED_{50} > 100 µg/larva EC_{50} > 649.4 mg/kg NOED ≥ 100.0 µg/larva NOEC≥ 649.4 mg/kg	IPO Pszczyna Study code: B/07/22 OECD 239

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the "EFSA Guidance Document on the risk assessment of plant protection products on bees", as provided in EFSA Journal 2013;11(7):3295.

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of Mezot 100 SC.

Intended use			
Active substance	Mesotrione		
Application rate (g/ha)	1 × 150		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	11	150	13,63

Contact toxicity	100		1,5
Product **Application rate (g/ha)**	Mezot 100 SC 1 × 1626		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	200	1626*	8,13
Contact toxicity	200		8,13

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
* based on density of formulation – Mezot 100 SC = 1.084 g/ml (dRR Secion 1)

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Tests are not required as the test substance is of low toxicity to honey bees.

9.6.4 Effects on solitary bees

Tests are not required as the test substance is of low toxicity to honey bees.

9.6.5 Overall conclusions

The test substance is of low toxicity to honey bees. Both criteria are met.

zRMS comments:

The HQ values are lower than the trigger of 50, indicating low risk to bees from following application of **Mezot 100 SC.** In addition, the chronic study for adult bees and a study effects on honey bee development and other honey bee life stages have been submitted by Applicant. The studies were accepted by RMS. The risk assessment based on this studies should be considered when GD for Bees, 2013 is implemented at EU level. Final decision should be taken into account at MSs level.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

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

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results [g/ha]	Reference
Typhlodromus pyri (protonymphs)	Mezot 100 SC	Laboratory test plates (2D)	LR_{50} = 1290 ER_{50} = 434	IPO Pszczyna Study code: B/29/19 ESCORT
Aphidius rhopalosiphi (adults)	Mezot 100 SC	Laboratory test plates (2D)	LR_{50} = 1052 ER_{50} = 1377	IPO Pszczyna Study code: B/30/19 ESCORT

zRMS comment:

zRMS agrees with the toxicity endpoints proposal by the Applicant.

9.7.1.1 Justification for new endpoints

9.7.2 Risk assessment

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).

9.7.2.1 Risk assessment for in-field exposure

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of Mezot 100 SC

Intended use	Maize		
Active substance/product	Mesotrione/Mezot 100 SC		
Application rate (g/ha)	1 × 1626		
MAF	1,0		
Test species Tier I	**LR_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1290	1626	1,26
Aphidius rhopalosiphi	1052		1,55

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.
Criteria values shown in bold breach the relevant trigger.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.2 Risk assessment for off-field exposure

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Mezot 100 SC

Intended use	Maize
Active substance/product	Mesotrione/Mezot 100 SC
Application rate (g/ha)	1 × 1626

MAF	1,0
vdf	10

Test species Tier I	**LR_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	1290	2,77	4,5	10	0,035
Aphidius rhopalosiphi	1052				0,043

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

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

zRMS comments: 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). The calculations are given in the table below. A low risk is demonstrated to the 2 standard first tier.

Intended use	**Maize (field crop scenario)**
Active substance/product	**Mesotrione/Mezot 100 SC**
Application rate (g/ha)	**1 × 1626**
MAF	**1**
VDF	**5 for 2-D study and 1 for 3-D**

Test species Tier II	**LR_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 1**
Typhlodromus pyri (2-D)	1290	2.77%	9.0	5	0.007
Aphidius rhopalosiphi (2-D)	1052		9.0		0.009

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

The calculations are given in the table below. A low risk is demonstrated to the 2 standard first tier.
A low risk is demonstrated to the 2 standard first tier.
zRMS for the first level risk assessment took into account the LR_{50} value for both indicator species, i.e. *T.pyri* and *A.rhopalosiphi* based on mortality parameter. A low in-field and off-field risk is demonstrated

for non-target arthropods - such as - *Typhlodromus pyri, Aphidius rhopalosiphi* at 1-tier RA (laboratory studies).

However, due to the current findings, which are made during the harmonization meetings of the central zone, the RMS would like to emphasize that in the case of the *A.rhopalosiphi* study, a statistically significant effect on reproduction of 83% was noted already for the dose of 0.75 L/ha. zRMS points out that it is necessary to consider the risk to non-target arthropods at Member State level. Perhaps at the level of national registrations in other countries, additional data will be required to clarify the effect of the plant protection product Mezot 100 SC on reproduction in additional studies, e.g. extended laboratory study for *A.rhopalosiphi.*

The risk assessment for *A.rhopalosiphi* and *T.pyri* should be considered by MSs level.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

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. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
~~*Eisenia fetida*~~	~~Mesotrione~~	~~14 d, Acute~~	~~LC_{50} = 2000 mg/kg dw~~	~~EFSA Conclusion~~
~~*Eisenia fetida*~~	~~MNBA~~	~~Acute~~	~~LC_{50} > 1000 mg/kg dw~~	~~EFSA Conclusion~~
Eisenia fetida	MNBA	Chronic	NOEC = 1050 mg/kg dw	EFSA Conclusion
Eisenia fetida	AMBA	Chronic	NOEC = 1050 mg/kg dw	EFSA Conclusion
Eisenia andrei	Mezot 100 SC Mesotrione	28 d, Chronic	NOEC = 56 mg/kg dw NOEC = 5,45 mg/kg dw	IPO Pszczyna Study code: G/64/19

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.2 Risk assessment

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).

9.8.2.1 First-tier risk assessment

The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2 and data for metabolites from DAR for Mesotrione.

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of Mezot 100 SC.

Intended use	Maize		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
Mesotrione	2000	0,150	13333
MNBA	1000	0,062	16129
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
MNBA AMBA	1050 1050	0,062 0,009	16936 116667
Mesotrione (Mezot 100 SC) Reproduction parameter	5,45	0,150	36,3
Mesotrione (Mezot 100 SC) Survival parameter	1.75	0.150	11.6

TER values shown in bold fall below the relevant trigger.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

Use of Mezot 100 SC indicate low risk for earthworms and other macroorganisms.

zRMS comment: Agreed.

Risk assessment for earthworms

Risk for earthworms for formulation Mezot 100 SC is low. No additional calculations for earthworms are needed.

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).

According to Regulation 284/2013 the acute risk assessment for earthworms for mesotrione and metabolite MNBA is not needed.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Mesotrione and Mezot 100 SC. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

9.9.1.1 Endpoints and effect values relevant to usew of Mezot 100 SC

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Mezot 100 SC Mesotrione	28 d, aerobic soil type	8,22 mg/kg < 25 % effect 0,80 mg as/kg < 25 % effect	IPO Pszczyna Study code: G/65/19

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms 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), Chapter 8.7.2 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of Mezot 100 SC

Intended use	Maize		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Mesotrione	0,80 (at 28 d)	0,150	Yes
Mezot 100 SC	8,22 (at 28 d)	1,630	Yes

9.9.3 Overall conclusions

On the basis of the results, it was concluded that Mezot 100 SC at the concentrations corresponding to 5 x PEC (14,32 mg/kg of soil), did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

zRMS comments:

The risk assessment for soil micro-organism after exposure of **Mezot 100 SC** has been accepted by the zRMS. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECs for the maximum application rate of **Mezot 100 SC**. The results indicate no adverse effect on nitrogen transformation even at soil concentrations well higher than the ones expected following application of **Mezot 100 SC.**

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

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.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants - Seedling emergence studies

Species	Substance	Exposure System	Results ER_{50} [g/ha]	Reference
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa).*	Mesotrione (Mezot 100 SC)	Seedling emergence: Plant number at the end of the experiment	159,9 159,9 155,0 30,5 159,9 159,9	[redacted]
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa).*		Seedling emergence: Shoot length (plants without roots)	21,4 100,3 10,3 54,9 159,9 159,9	
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa).*		Seedling emergence: Plant dry weight (plants without roots)	10,2 14,7 8,6 9,6 159,9 159,9	

Table 9.10-2: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants - Vegetative Vigour studies

Species	Substance	Exposure System	Results ER_{50} [g/ha]	Reference
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa).*	Mesotrione (Mezot 100 SC)	Vegetative vigour: Plant number at the end of the experiment	159,9 159,9 159,9 159,9 159,9 159,9	[redacted]
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa).*		Vegetative vigour: Shoot length (plants without roots)	13,64 33,45 4,97 15,57 159,9 159,9	
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa).*		Vegetative vigour: Plant dry weight (plants without roots)	1,55 2,49 5,10 7,73 153,26 98,77	

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

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.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of Mezot 100 SC

Intended use	Maize		
Active substance/product	Mezot 100 SC		
Application rate [g/ha]	150		
MAF	1		
ER_{50} (g/ha) Vegetative vigour: Plant dry weight - Pea	**Drift rate**	**$PER_{off\text{-}field}$ (mg/kg)**	**TER** **Criterion: TER ≥ 5**
1,55	0,00277 (1 m)	0,416	3,73
1,55	0,00057 (5 m)	0,086	18,02

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

In order to protect plants which are not the target, it is necessary to designate a protection zone 5 m wide from the land not used for agriculture.

9.10.3 Overall conclusions

Use of Mezot 100 SC is accepted concerning effects on non-target terrestrial plants.

zRMS comment:

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. The deterministic risk based on the ER_{50} = 1.55 g mesotrione/ha value *(Pea)* from vegetative vigour test and $PER_{off\text{-}field}$, indicated needs for further refinement.
The risk following mitigation measures are proposed: **Mezot 100 SC** achieve the acceptability criteria TER ≥ 5 with applying:
- 5 m buffer zone without drift-reducing nozzles

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No additional data.

9.12 Monitoring data (KCP 10.8)

No additional data.

9.13 Classification and Labelling

With regard to ecotoxicological data – H410 - Very toxic to aquatic life with long lasting effects.

zRMS comment: Agreed.

CLASSIFICATION	
Hazard class(es), categories:	Aquatic Acute 1 Aquatic chronic 1
LABELLING	

Hazard pictograms:	 GHS09
Signal word:	Warning
Hazard statement(s):	H410 - Very toxic to aquatic life with long lasting effects H 400 - Very toxic to aquatic life
Precautionary statement(s):	P391 - Collect spillage. P501 - Dispose of contents/container in accordance to national regulations.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.1.2/01	Karol Łukaszewski	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	Y	Elvita Sp. z o.o.
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	Elvita Sp. z o.o.
KCP 10.2.1	[redacted]	2019	MEZOT 100 SC Rainbow trout, Acute toxicity test [redacted]	Y	Elvita Sp. z o.o.
KCP 10.2.1	Ewa Nierzędska	2019	MEZOT 100 SC Daphnia magna, Acute Immobilization Test IPO Pszczyna W/33/19 GLP/No Published	Y	Elvita Sp. z o.o.
KCP 10.2.1	Ewa Nierzędska	2019	MEZOT 100 SC Pseudokirchneriella subcapitata SAG 61.81 Growth Inhibition Test IPO Pszczyna W/34/19 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.2.1	Ewa Nierzędska	2019	MEZOT 100 SC Lemna gibba CPCC 310 Growth Inhibition Test IPO Pszczyna	N	Elvita Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			W/35/19 GLP/No Published		
KCP 10.3.1.1.1	Mateusz Grzesica	2019	Mezot 100 SC Honeybees (Apis mellifera L.), Acute Oral Toxicity Test IPO Pszczyna B/34/19 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.3.1.1.2	Mateusz Grzesica	2019	MEZOT 100 SC Honeybees (Apis mellifera L.), Acute Contact Toxicity Test IPO Pszczyna B/35/19 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.3.1.3/01	Elżbieta Kulec-Płoszczyca	2019	Mezot 100 SC Honeybees (Apis mellifera L.), Larval Toxicity Test, Single Exposure IPO Pszczyna B/31/19 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.3.1.3/02	Elżbieta Kulec-Płoszczyca	2022	Mezot 100 SC Honeybees (Apis mellifera L.), Larval Toxicity Test, RepeatedExposure IPO Pszczyna B/07/22 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.3.1.2	Elżbieta Kulec-Płoszczyca	2019	Mezot 100 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test IPO Pszczyna B/33/19 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.4.1.1	Paweł Pieczka	2020	MEZOT 100 SC Earthworm Reproduction Test IPO Pszczyna G/64/19 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.5	Paweł Pieczka	2020	MEZOT 100 SC Soil Microorganisms: Nitrogen Transformation Test IPO Pszczyna G/65/19	N	Elvita Sp. z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP/No Published		
KCP 10.3.2	Monika Stalmach	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	Elvita Sp. z o.o.
KCP 10.3.2	Monika Stalmach	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	Elvita Sp. z o.o.
KCP 10.6	Magdalena Wołany	2020	MEZOT 100 SC Terrestial Plant Test: Seedling Emergence and Seedling Growth Test. IPO Pszczyna G/62/19 GLP/No Published	N	Elvita Sp. z o.o.
KCP 10.6	Magdalena Wołany	2020	MEZOT 100 SC Terrestrial Plant Test: Vegetative Vigour Test. IPO Pszczyna G/63/19 GLP/No Published	N	Elvita Sp. z o.o.

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

No studies submitted.

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

No studies submitted.

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No additional studies submitted.

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Comments of zRMS:	Study was carried out according to appropriate OECD 203 and all validity criteria were met. **Deviation from the study**: 1. The first deviation regards to the stability, which was exceeded by 1°C from the recommended in study plan, guideline and SOP/W/24. 2. The second deviation regards improper date of validity of the test item in the study plan. In the study plan stated that the date of the validity of the test item is May, 2020, whereas the proper date in the Certificate of Analysis is May, 2021. In opinion zRMS, above deviations did not affect the study results. The validity criteria: The following validity criteria specified in the OECD Guideline No. 203 (2019) were met: - the mortality in the control was 0% at exposure termination (should not exceed 10% or 1 fish if less than 10 fish are used); - dissolved oxygen concentrations were within the range of 91 – 98% of air saturation value (obligatory above 60% of air saturation value). The study is considered acceptable. **Agreed endpoints:**

	The LC_{50} value after 96 h of exposure is 6.72 mg formulation/L The LOEC/96 h value is 10 mg formulation/L The NOEC/96 h value is 4.54 mg formulation/L

Report:	**10.2.1/01,** [redacted]
Title:	Mezot 100 SC; Rainbow trout, Acute toxicity test
Document No:	[redacted]
Guidelines:	OECD 203
GLP	YES

Test item: Mezot 100 SC, batch number: 190521; date of production: 05.2019
Test organism: Rainbow trout (Oncorhynchus mykiss Walb.),
Test design: Static system (96 h of exposure), one replicate, ten fish in each aquarium, the ratio of fish weight per volume (10 L) was 0.41 g/L.
Test item concentrations: 10, 4.54, 2.07, 0.94, 0.43, 0.19 mg/L plus the control.
Test conditions: Temperature of water: 11 – 14 ºC; pH of the control: 7.27 – 7.86; dissolved oxygen concentration: 91 – 98 % of air saturation value; lighting daily cycle: 16 h light : 8 h dark; no feeding; constant aeration.
Chemical determinations: The concentrations of Mesotrione were determined using a liquid chromatographic method with DAD detection.

Concentration and stability of mesotrione, definitive test

Nominal test item concentration [mg/L]	Nominal concentration of mesotrione [mg/L]	Average concentration (n=3) of mesotrione measured in samples collected [mg/L]			
		at exposure initiation	% of the nominal concentration	at exposure termination	% of the nominal concentration
Control	---	<LoD	---	<LoD	---
0.19	0.0185	0.0159	85.9	0.0160	86.5
0.43	0.0419	0.0383	91.4	0.0382	91.2
0.94	0.0915	0.0778	85.0	0.0779	85.1
2.07	0.202	0.190	94.1	0.190	94.1
4.54	0.442	0.400	90.5	0.400	90.5
10	0.974	0.896	92.0	0.886	91.0

LoQ = 0.001 mg/L
LoD = 0.0003 mg/L

Endpoint values based on the nominal test item concentrations and mortality of fish - definitive test

Endpoint values [mg/L]	Time of exposure			
	24 h	48 h	72 h	96 h
LC_{50}	9.25 (n.d.)	8.70 (n.d.)	6.72 (n.d.)	6.72 (n.d.)
NOEC	4.54	4.54	4.54	4.54
LOEC	10	10	10	10

Calculations according to [6]. [SOP/W/68].
(n.d.) not determined

Results:
The endpoint values determined on the basis of the nominal test item concentrations and mortality of fish are given below:
The LC50 value after 96 h of exposure is 6.72 mg/L.
The LOEC/96 h value is 10 mg/L.
The NOEC/96 h value is 4.54 mg/L.

Comments of zRMS:	Study was carried out according to appropriate OECD 202 and all validity criteria were met. In the definitive test the validity criteria were met according to OECD Guideline No. 202 (2004): - the percentage of immobilisation of *Daphnia magna* in the control was 0% (criterion: not more than 10%), - the dissolved oxygen concentrations in the test vessels were within the range of 8.2 – 9.5 mg/L (criterion: not less than 3 mg/L). **Deviation from the study**: The date of the expiry of the test item was May 2020 but it should be stated May 2021. Deviation did not affect the study results. The study is considered acceptable. **Agreed endpoints expressed as mg formulation/L:**

Endpoint values based on the nominal test item concentration - definitive test

Endpoint value [mg/L]	Time of exposure	
	24 h	48 h
EC_{50}	41.50 (30.12 – 62.32)	16.91 (13.49 – 21.08)
EC_{20}	16.16 (9.25 – 22.77)	10.28 (7.14 – 12.96)
EC_{10}	9.87 (4.45 – 15.07)	7.92 (4.95 – 10.39)
LOEC	12.50	12.50
NOEC	6.30	6.30

Report:	**10.2.1/02, Ewa Nierzędska, 2019**
Title:	Mezot 100 SC Daphnia magna, Acute Immobilization Test
Document No:	W/33/19
Guidelines:	OECD 202
GLP	YES

Test item: Mezot 100 SC, batch number: 190521;; date of production: 05.2019
Test organism: Daphnia magna Straus
Test design: Static test (48 hours); 4 replicates per each test item concentration and the control; 5 daphnids in each replicate.
Nominal test item concentrations: 100, 50, 25, 12.5, 6.3 mg/L plus the control.
Test conditions Temperature: 20,4 – 21,5 ºC; pH of the control: 7.26 – 7.37; dissolved oxygen concentration: 8.7 – 8.9 mg/L; 16 hours light : 8 hours dark; fluorescent light source; no feeding; no aeration.
Chemical determinations: The concentration of Mesotrione was determined with a validated liquid chromatographic method with DAD detection.

Concentration and stability of mesotrione, definitive test

Nominal test item concentration [mg/L]	Nominal concentration of mesotrione [mg/L]	Average determined concentration of mesotrione (n=3) in samples collected [mg/L]			
		at exposure initiation	% of nominal concentration	at exposure termination	% of nominal concentration
Control	---	<LoD	---	<LoD	---
6.3	0.613	0.572	93.3	0.578	94.3
12.5	1.22	1.14	93.4	1.15	94.3
25	2.43	2.33	95.9	2.41	99.2
50	4.86	4.69	96.5	4.83	99.4
100	9.72	9.30	95.7	9.72	100.0

LoQ = 0.001 mg/L
LoD = 0.0003 mg/L
--- no value

pH values and dissolved oxygen concentrations, definitive test

Nominal test item concentration [mg/L]	Measured at exposure initiation #		Measured at exposure termination *	
	pH value	Dissolved oxygen concentration [mg/L]	pH value	Dissolved oxygen concentration [mg/L]
Control	7.37	8.9	7.26	8.7
6.3	7.36	9.0	7.32	8.4
12.5	7.32	9.0	7.30	8.6
25	7.29	9.0	7.29	8.4
50	7.16	9.0	7.29	8.2
100	7.07	9.5	7.27	9.1

#- pH values and dissolved oxygen concentrations measured in samples before split up into replicates
*- pH values and dissolved oxygen concentrations measured in samples of pooled replicates

Immobilisation of *Daphnia magna*, definitive test

Nominal test item concentration [mg/L]	Number of *Daphnia magna*	Number of immobilised *Daphnia magna*								Total of immobilised *Daphnia magna* [%]	
		24 h				48 h					
		Replicates									
		A	B	C	D	A	B	C	D	24 h	48 h
Control	20	0	0	0	0	0	0	0	0	0	0
6.3	20	0	0	0	1	0	0	0	1	5	5
12.5	20	1	0	2	1	2	0	2	3	20	35
25	20	0	0	3	2	3	3	3	4	25	65
50	20	1	3	3	3	5	5	5	5	50	100
100	20	4	5	4	4	5	5	5	5	85	100

Time of exposure: 08.01.2020 – 10.01.2020

Results:
The endpoint values determined on the basis of the nominal test item concentrations are given below:
The EC50/48 h is higher than 16.91 mg/L (95% confidence limit: 13.49 – 21.08).
The LOEC value is 12.5 mg/L.
The NOEC value is 6.3 mg/L.

Comments of zRMS:	Study was carried out according to appropriate OECD 201 and all validity criteria were met. In the definitive test, the following validity criteria specified in the OECD Guideline No. 201 (2006) were met: - the biomass in the control increased by a factor of 140.6 within the 72-hour test period (criterion: at least a 16-fold growth), - the coefficient of variation of the mean specific growth rate after the 72-hour test period (exposure initiation – exposure termination) in the control culture was 1.1% (criterion: it must not exceed 7%). - the mean coefficient of variation for the section-by-section growth rate in the control culture was 33.5% (criterion: it must not exceed 35%). **Deviation from the study**: none

	The study is considered acceptable. **Agreed endpoints expressed as mg formulation/L:** The E_rC_{50}/72 h value is 21.11 mg/L (95% confidence interval: 18.68 – 23.84). The LOEC/72 h and the NOEC/72 h values for growth rate could not be calculated on basis of obtained results. The E_yC_{50}/72 h value is 5.50 mg/L (95% confidence interval: 4.58 – 6.60). The LOEC/72 h value for yield is 10 mg/L. The NOEC/72 h value for yield is 3.2 mg/L. **EC_{10}/EC_{20} calculation:** 72h E_yC_{10} = 1.447 mg/L (95% confidence interval: 0.902-1.964). 72h E_yC_{20} = 2.288 mg/L (95% confidence interval: 1.620-2.897). 72h E_rC_{10} = 5.078mg/L (95% confidence interval: 3.803-6.330). 72h E_rC_{20} = 8.281 mg/L (95% confidence interval: 6.689-9.799).
Report:	**10.2.1/03, Ewa Nierzędska, 2019**
Title:	Mezot 100 SC ~~*Pseudokirchneriella subcapitata*~~ *Raphidocelis subcapitata* SAG 61.81 Growth Inhibition Test
Document No:	W/34/19
Guidelines:	OECD 201
GLP	YES

Test item: Mezot 100 SC, batch number: 190521;; date of production: 05.2019
Test organism: The unicellular freshwater green algae, ~~*Pseudokirchneriella subcapitata*~~ *Raphidocelis subcapitata*
Test design: 72 hours of the exposure; three replicates of each test item concentration and six replicates of the control; initial algal cell density: 1 x 10^4 cells/mL.
Test item concentrations: 100, 32, 10, 3.2, 1.0 mg/L plus the control.
Test conditions: Temperature: 21,2 – 22.1 ºC; pH of the control: 7.67 – 7.87; average light intensity: 5788 – 6202 lux; constant illumination and shaking; the AAP medium.
Chemical analysis: The concentration of Mesotrione was determined with a validated liquid chromatographic method with DAD detection.
Results:
The ErC50/72 h value is 21.11 mg/L (95% confidence interval: 18.68 – 23.84).
The LOEC/72 h and the NOEC/72 h values for growth rate could not be calculated on basis of obtained results.
The EyC50/72 h value is 5.50 mg/L (95% confidence interval: 4.58 – 6.60).
The LOEC/72 h value for yield is 10 mg/L.
The NOEC/72 h value for yield is 3.2 mg/L.

Comments of zRMS:	Study was carried out according to appropriate OECD 221 and all validity criteria were met. In the definitive test, the following validity criteria specified in the OECD Guideline No. 221 (2006) were met: - The doubling time of frond number in the control was 2.1 days, criterion: less than 2.5 days (the factor of frond number in the control between 0 and 7 day was 9.9). - The average specific growth rate in the control between day 0 and day 7 was 0.327 d^{-1} (minimum requirement: higher than 0.275 d^{-1}).

Deviation from the study: none

The study is considered acceptable.

Agreed endpoints expressed as mg formulation/L:

Endpoint values of growth rate based on the nominal test item concentrations [mg/L] - definitive test

Endpoint values	Frond number			Dry weight
	0-2 d	0-4 d	0-7 d	0-7 d
E_rC_{50}	0.855 (0.360 – 1.973)	0.164 (0.107 – 0.249)	0.572 (0.339 – 0.943)	10.023 (4.135 – 43.907)
E_rC_{20}	0.030 (0.003 – 0.097)	0.046 (0.018 – 0.075)	0.049 (0.016 – 0.100)	0.031 (0.002 – 0.113)
E_rC_{10}	n.d.	0.023 (0.006 – 0.045)	0.014 (0.003 – 0.035)	n.d.
LOEC	0.100	0.100	0.100	0.100
NOEC	0.032	0.032	0.032	0.032

Calculations according to [4]. [SOP/W/68]
(-) 95% confidence interval

Endpoint values of yield based on the nominal test item concentrations [mg/L] - definitive test

Endpoint values	Frond number			Dry weight
	0-2 d	0-4 d	0-7 d	0-7 d
E_yC_{50}	0.335 (0.157 – 0.651)	0.083 (0.071 – 0.098)	0.132 (0.102 – 0.170)	0.143 (0.044 – 0.314)
E_yC_{20}	0.026 (0.004 – 0.068)	0.043 (0.031 – 0.053)	0.040 (0.024 – 0.056)	n.d.
E_yC_{10}	n.d.	0.030 (0.019 – 0.040)	0.021 (0.010 – 0.033)	n.d.
LOEC	0.100	≤0.032	≤0.032	0.100
NOEC	0.032	<0.032	<0.032	0.032

Calculations according to [4]. [SOP/W/68]
(-) 95% confidence interval

7d EC_{10}/EC_{20} calculation:
Frond number:
7d E_rC_{20} = 0.049 mg/L (95% confidence interval: 0.016 – 0.100).
7d E_rC_{10} = 0.014 mg/L (95% confidence interval: 0.003 – 0.035).
7d E_yC_{20} = 0.040 mg/L (95% confidence interval: 0.024 – 0.056).
7d E_yC_{10} = 0.021 mg/L (95% confidence interval: 0.010 – 0.033).

Dry weight:
7d E_rC_{20} = 0.031 mg/L (95% confidence interval: 0.002 – 0.113).
7d E_rC_{10} value was not determined due to mathematical reasons.
7d E_yC_{20} and 7d E_yC_{10} values were not determined due to mathematical reasons.

Report:	**10.2.1/04, Ewa Nierzędska, 2019**
Title:	Mezot 100 SC Lemna gibba CPCC 310, Growth inhibition test

Document No:	W/35/19
Guidelines:	OECD 221
GLP	YES

Test item: Mezot 100 SC, batch number: 190521;; date of production: 05.2019
Test organism: The freshwater aquatic plant, Lemna gibba CPCC 310
Test design: Static system; 7 days of exposure; three replicates for each test item concentration and six replicates for control.
Test item concentrations: 32, 10, 3.2, 1.0, 0.32, 0.10, 0.032 mg/L plus the control.
Test conditions: Temperature: 23,4 – 23,8 ºC; pH of the control: 7.43 – 8,93; average light intensity: 8134 – 8322 lux; constant illumination.
Chemical analysis: The concentration of Mesotrione was determined with a validated liquid chromatographic method with DAD detection.
Results:
Endpoints based on the frond number:
The ErC50/7 d value is 0.572 mg/L (95% confidence interval 0.339 – 0.943).
The EyC50/7 d value is 0.132 mg/L (95% confidence interval 0.102 – 0.170).
For growth rate the NOEC/7 d is 0.032 mg/L, whereas the LOEC/7 d value is 0.100 mg/L.
For yield the NOEC/7 d value is lower than 0.032 mg/L, whereas the LOEC/7 d value lower than or equal to 0.032 mg/L
Endpoints based on the dry weight:
The ErC50/7 d value is 10.023 mg/L (95% confidence interval 4.135 – 43.907).
The EyC50/7 d value is 0.143 mg/L (95% confidence interval 0.044 – 0.314).
For growth rate and yield the NOEC/7 d value is 0.032 mg/L and the LOEC/7 d value is 0.100 mg/L.

Amendment:
Endpoint values
The endpoint values were determined based on the nominal test item concentrations. The ECx values were calculated with the probit method. The lowest observed effect concentration (LOEC) and the no observed effect concentration (NOEC) were estimated on the basis of the results of statistical analyses. To make calculations and to conduct statistical analyses, the ToxRat Professional commercial software was used. The endpoint values determined based on the nominal test item concentrations:
The median concentration causing 50% inhibition of the mean specific growth rate of Lemna gibba determined on the basis of the frond number ErC50/7 d value is 0.572 mg/L (95% confidence interval: 0.339 – 0.943). The ErC20/7 d value is 0.049 mg/L (95% confidence interval: 0.016 – 0.100) and the ErC10/7 d value is 0.014 mg/L (95% confidence interval: 0.003 – 0.035).
The growth rate data based on the frond number were analyzed using Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous, and the Williams Multiple Sequential t-test Procedure which showed significant differences between nominal test item concentrations in the range of 0.1 – 32 mg/L and the control. The LOEC/7 d value is 0.100 mg/L and NOEC/7 d value is 0.032 mg/L.
The median concentration causing 50% inhibition of yield of Lemna gibba determined on the basis of the frond number EyC50/7 d value is 0.132 mg/L (95% confidence interval: 0.102 – 0.170). The EyC20/7 d is 0.040 mg/L (95% confidence interval: 0.024 – 0.056) and the EyC10/7 d value is 0.021 mg/L (95% confidence interval: 0.010 – 0.033).
The yield data based on the frond number were analyzed using Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were

homogeneous, and the Williams Multiple Sequential t-test Procedure which showed significant differences for all nominal test item concentrations in the range of 0.032 – 32 mg/L and the control. The lowest test item concentration causing a yield inhibition effect, i.e. the LOEC/7 d value is equal to or lower than 0.032 mg/L. The highest test item concentration at which no yield inhibition effects are observed, i.e. the NOEC/7 d value is lower than 0.032 mg/L.
The median concentration causing 50% inhibition of the mean specific growth rate of Lemna gibba determined on the basis of the dry weight ErC50/7 d value is 10.023 mg/L (95% confidence interval: 4.135 – 43.907). The ErC20/7 d value is 0.031 mg/L (95% confidence interval: 0.002 – 0.113). The ErC10/7 d value was not determined due to mathematical reasons.
The growth rate data based on the dry weight were analyzed using Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous, and Williams Multiple Sequential t-test Procedure showed significant differences for nominal test item concentrations 0.100 and 32 mg/L and the control. The LOEC/7 d value is 0.100 mg/L and NOEC/7 d value is 0.032 mg/L.
The median concentration causing 50% inhibition of yield of Lemna gibba determined on the basis of the dry weight EyC50/7 d value is 0.143 mg/L (95% confidence interval: 0.044 – 0.314). The EyC20/7 d and the EyC10/7 d values were not determined due to mathematical reasons.
The yield data based on the dry weight were analyzed using the Shapiro-Wilk's Test on Normal Distribution which confirmed normal distribution of the data, Levene's Test on Variance Homogeneity (with Residuals) which showed that the variances were homogeneous, and Williams Multiple Sequential t-test Procedure which showed significant differences for nominal test item concentrations in the range 0.10 – 32 mg/L and the control. The lowest test item concentration causing a yield inhibition effect, i.e. the LOEC/7 d value is 0.10 mg/L. The highest test item concentration at which no yield inhibition effects are observed, i.e. the NOEC/7 d value is 0.032 mg/L.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

Comments of zRMS:	Study was carried out according to appropriate OECD 213 and all validity criteria were met. **The following validity criteria were met during the test:** - the average mortality for the control was 0.0% at the end of the experiment (criterion: it must not exceed 10%). - the LD_{50}/24 h of the reference item (dimethoate) was 0.27 µg a.i./bee (criterion: 0.10 – 0.35 µg a.i./bee).

Deviation from the study: none
The study is considered acceptable.

Agreed endpoints:

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h		LD_{50} after 48 h [µg/bee]
		Total		
		[no.]	[%]	
0.0 (Control)	30	0	0.0	> 200
25.0	30	1	3.3	
50.0	30	0	0.0	
100.0	30	0	0.0	
200.0	30	5	16.7	

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Report:	**10.3.1.1.1/01, Mateusz Grzesica, 2019**
Title:	Mezot 100 SC Honeybees (Apis mellifera L.), Acute Oral Toxicity Test
Document No:	B/34/19
Guidelines:	OECD 213
GLP	YES

Test item: Mezot 100 SC, batch number: 190521; date of production: 21.05.2019
Biological test system: the honeybee, Apis mellifera L.,
Test design:
- the test item:
exposure duration: 48 hours
number of doses: 4 doses and a control
number of replicates: 3 replicates
number of bees: 10 bees/replicate
- the reference item:
exposure duration: 24 hours
number of doses: 3 doses
number of replicates: 3 replicates
number of bees: 10 bees/replicate
Test item doses: 25.0, 50.0, 100.0, and 200.0 µg test item/bee and a control (0.0 µg/bee)
Reference item doses: 0.1, 0.2 and 0.4 µg a.i./bee and a control (0.0 µg/bee)
Test conditions:
temperature: 24 – 26 ºC
relative air humidity: 62 – 67 %
place: a dark room
Results:
The median lethal doses (LD50 24 h and LD50 48 h) are higher than the maximum used dose,

i.e. 200 µg test item/honeybee.

Comments of zRMS:

Study was carried out according to appropriate OECD 214 and all validity criteria were met.

The following validity criteria were met during the test:
- the average mortality for the control was 3.3% after 48 h (criterion: it must not exceed 10%),
- the LD_{50}/24 h of the reference item (dimethoate) was 0.25 µg a.i./bee (criterion: 0.10−0.30 µg a.i./bee).

Deviation from the study: none
The study is considered acceptable.

Agreed endpoints:

Dose [µg/bee]	Number of tested bees [no.]	Mortality after 48 h after the beginning of the treatment			LD_{50} [µg/bee]
		Total			
		[no.]	[%]	[%][a]	
0.0 (Control)	30	1	3.3	–	> 200.0
25.0	30	1	3.3	0.0	
50.0	30	0	0.0	0.0	
100.0	30	2	6.7	3.5	
200.0	30	1	3.3	0.0	

[a]: mortality corrected using the formula of Abbott [10]

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Report:	**10.3.1.1.1/02, Mateusz Grzesica, 2019**
Title:	Mezot 100 SC Honeybees (Apis mellifera L.), Acute Contact Toxicity Test
Document No:	B/35/19
Guidelines:	OECD 214
GLP	YES

Test item: Mezot 100 SC, batch number: 190521; date of production: 21.05.2019
Biological test system: the honeybee, Apis mellifera L.,
Test design:
- the test item:
exposure duration: 48 hours
number of doses: 4 doses and a control
number of replicates: 3 replicates
number of bees: 10 bees/replicate

- the reference item:
exposure duration: 24 hours
number of doses: 3 doses
number of replicates: 3 replicates
number of bees: 10 bees/replicate
Test item doses: 25.0, 50.0, 100.0 and 200.0 µg test item/bee and a control (0.0 µg/bee)
Reference item doses: 0.1, 0.2 and 0.4 µg a.i./bee and a control (0.0 µg/bee)
Test conditions:
temperature: 24 – 25 ºC
relative air humidity: 62 – 67 %
place: a dark room

Results:
The median lethal doses (LD50 24 h and LD50 48 h) are higher than the maximum used dose, i.e. 200 µg test item/honeybee.

Comments of zRMS:

Study was carried out according to appropriate OECD 245 and all validity criteria were met.

The following validity criteria were met during the test:
- At the end of the experiment average mortality of the control groups was 0.0% (criterion: it must not exceed 15%).
- After 10 days of exposure corrected mortality of the honeybees exposed to the reference item at the concentration of 0.75 mg/kg (0.014 µg/bee/day) was 50.0%.

Deviation from the study: According to the documents mentioned above, the recommended range of relative air humidity is 50–70%. However, in the definitive test, relative air humidity was higher, i.e. 71%. This short term deviation (<2h) did not have an impact on the results of the study.

The study is considered acceptable.

Agreed endpoints:

The effects of Mezot 100 SC on mortality of honey bees are summarized below:

Nominal test item dose [µg/bee/day]	Nominal test item concentration [mg/kg]	Consumed[a] dose [µg/bee/day]	Number of tested bees [no]	Total mortality		LC_{50} [mg/kg]	LDD_{50} [µg/bee/day]
				No.	[%]		
Mezot 100 SC							
0.0 (Control)			50	0	**0.0**	**> 667**	**> 11.7**
20.0	**667**	11.7	50	0	**0.0**		
Dimethoate (reference item)							
0.0225	**0.75**	0.014	30	15	**50.0**	not determined	

[a]: ingested doses (dietary doses) were calculated on the basis of the concentrations of the test item / reference item and average sucrose solution consumption

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Report:	**10.3.1.2/01, Elżbieta Kulec-Płoszczyca, 2019**
Title:	Mezot 100 SC Honeybees (Apis mellifera L.), Chronic Oral Toxicity Test
Document No:	B/33/19
Guidelines:	OECD 245
GLP	YES

Test item: Mezot 100 SC, batch number: 190521; date of production: 21.05.2019
Biological test system: the honeybee, Apis mellifera L.,
Test design:
- the test item:
number of concentrations: 1 and the control
number of replicates: 5
number of insects: 10 bees/replicate
- the reference item:
number of concentrations: 1
number of replicates: 3
number of insects: 10 bees/replicate
- exposure duration: 10 days
Nominal concentration of the test item: 667 mg/kg
Nominal dose of the test item: 20.0 µg/bee/day
Dose of the test item consumed by the bees (i.e. dietary dose): 11.7 µg/bee/day
Nominal concentration of the reference item (dimethoate): 0.75 mg/kg
Nominal dose of the reference item (dimethoate): 0.0225 µg/bee/day
Doses of the reference item consumed by the bees (i.e. dietary dose): 0.014 µg/bee/day
Test conditions:
temperature: 30.5 – 33.5 ºC
relative humidity: 53 – 71 %

Results:
The percentages of mortality of the honeybees exposed to the test item, Mezot 100 SC at the concentration of 667 mg/kg (dietary dose 11.7 µgbee/day) at each observation time (from day 1 to day 10) were 0.0%.
On the basis of the obtained mortality results the LC50 is higher than 667 mg/kg, and the LDD50 value is higher than 11.7 µg/bee/day.

Comments of zRMS:	Study was carried out according to appropriate OECD 237 and all validity criteria were met. **The following validity criteria were met during the test:** - Mortality of the control group was 5.6% at the end of the test (criterion: ≤ 15%). - Mortality of the larvae treated with the reference item (dimethoate) was 94.1% (corrected using Abbott's formula) (criterion: ≥ 50%). **Deviation from the study**: none. The study is considered acceptable. **Agreed endpoints:**

The effects of Mezot 100 SC on mortality of honey bee larvae are summarized below:

Dose [µg/larva]	Number of tested larvae [no.]	Mortality after 72 h of exposure (D7)			LD_{50} 72 h [µg/larva]
		Total			
		[no.]	[%]	Corrected[a] [%]	
Mezot 100 SC					
0.0 (Control)	36	2	**5.6**	-	**> 100.0**
6.25	36	2	**5.6**	**0.0**	
12.5	36	4	**11.1**	**5.9**	
25.0	36	4	**11.1**	**5.9**	
50.0	36	5	**13.9**	**8.8**	
100.0	36	9	**25.0**	**20.6**	
Dimethoate (reference item)					
8.8	36	34	**94.4**	**94.1**	not determined

[a]: Mortality corrected according to the Abbott formula

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Report:	**10.3.1.2/01, Elżbieta Kulec-Płoszczyca, 2019**
Title:	Mezot 100 SC Honeybees (Apis mellifera L.), Larval Toxicity Test, Single Exposure
Document No:	B/31/19
Guidelines:	OECD 237
GLP	YES

Test item: Mezot 100 SC, batch number: 190521; date of production: 21.05.2019
Biological test system: the honeybee, Apis mellifera L.,
Test design:
– the test item: exposure: 72 hours; number of doses: 5 and a control; number of replicates: 3; number of larvae: 12/replicate
– the reference item: exposure: 72 hours; number of doses: 1; number of replicates: 3; number of larvae: 12/replicate
Test item doses: 6.25, 12.5, 25.0, 50.0 and 100.0 µg/larva + control
Test conditions: temperature: 34.0 – 35.0 ºC; relative air humidity: 90.1 – 94.9%

Results:
Mortality of the control group at the end of the test was 5.6% (criterion: ≤ 15%). The percentages of corrected mortality of the honeybee larvae, exposed to the test item, Mezot 100 SC at the doses of 6.25, 12.5, 25.0, 50.0 and 100.0 µg/larva were: 0.0, 5.9, 5.9, 8.8 and 20.6%, respectively.
The median lethal doses after 24, 48 and 72 h of exposure, for the test item (LD50/24 h, LD50/48 h and LD50/72 h) are higher than the maximum used dose, i.e. 100 µg test item/larva.

Comments of zRMS:

Study was carried out according to appropriate OECD 239 and all validity criteria were met.

The following validity criteria were met during the test:

− Cumulative larval mortality in the control group was 0.0% at day 8 (D8) (criterion: ≤ 15%).
− Abbott corrected mortality of the larvae treated with the reference item at day 8 (D8) (dimethoate) was 97.2% (criterion: ≥ 50%).
− Emergence rate in the control group on D22 was 86.1% (criterion: ≥ 70%).

Deviations in the study:
The study was performed according to the OECD Guidance Document No. 239 (2021): 'Honeybees, larval toxicity test, repeated exposure', other references given in section 9, SOP's listed in section 10 of the report, and the study plan. There were no deviations from the documents mentioned above.

Agreed endpoints:

The effects of Mezot 100 SC on mortality of honey bee larvae are summarized below:

Dose [µg test item/larva]	Concentration [mg test item/kg food]	Number of tested larvae [no.]	Total mortality (larval and pupal) on day 22 (D22)				
			Number [no.]	[%]	Corr[a] [%]	Number of emerged adults [No.]	Emergence rate [%]
Test item: Mezot 100 SC							
0.0 (Control)		36	5	13.9	–	31	**86.1**
100.0	**649.4**	36	4	11.1	**-3.2**	32	**88.9**
ED_{50} [µg test item/larva]			**> 100.0**				
EC_{50} [mg/kg]			**> 649.4**				
NOED [µg test item/larva]			**≥ 100.0**				
NOEC [mg/kg]			**≥ 649.4**				
Reference item: Technical dimethoate mortality on day 8 (D8)							
7.39	**48.0**	36	35	97.2	**97.2**	not determined	

[a]: Mortality corrected according to the Abbott formula [7]

Report:	**10.3.1.2/02, Elżbieta Kulec-Płoszczyca, 2019**
Title:	Mezot 100 SC Honeybees (Apis mellifera L.), Larval Toxicity Test, Repeated Exposure
Document No:	B/07/22

Guidelines:	OECD 239
GLP	YES

Test item:
Mezot 100 SC content: 105.8 g/L of mesotrione (CAS No. 104206-82-8), batch no.: 01/22
production date: 01.2022, expiry date: 01.2024
Biological test system:
the honeybee, Apis mellifera L.; strain: carnica; source: an apiary at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; age: one-day-old larvae
Experimental design:
– the test item: number of cumulative dose: 1 and a control; number of replicates: 3; number of larvae: 12/replicate
– the reference item: number of cumulative doses: 1; number of replicates: 3; number of larvae: 12/replicate
Test item dose: 100.0 µg/larva + control
Reference item dose: 7.39 µg dimethoate/larva
Test duration: 22 days
Test conditions:
temperature: 34 – 34.9°C;
relative air humidity: D1 – D8: 91.3 – 98.0%
D8 – D15: 75.7 – 85.0%
D15 – D22: 52.5 – 79.4%
Results:
Mortality of the control group on day 8 (D8) of the test was 0.0% (criterion: ≤ 15%). The percentage of mortality of the honeybee larvae, exposed to the test item, Mezot 100 SC at the cumulative dose of 100.0 µg test item/larva at D8 was 0.0%. The percentage of larval mortality on D8 in the reference item group was 97.2%.
Pupal mortality of the control group on day 15 (D15) of the test was 8.3%. The percentage of mortality of the honeybee pupae corrected using Abbott's formula, exposed to the test item, Mezot 100 SC at the cumulative dose of 100.0 µg/larva at D15 was 3.0%. The percentage of pupal mortality, corrected using Abbott's formula, on D15 in the reference item group was 100.0%.
Cumulative mortality (larval and pupal) of the control group on day 22 (D22) of the test was 13.9%. The percentage of mortality of the honeybee pupae corrected using Abbott's formula, exposed to the test item, Mezot 100 SC at the cumulative dose of 100.0 µg/larva at D22 was (-3.2)%. The negative value indicates that mortality in the group treated with the test item was lower than in the control group. The percentage of pupal mortality, corrected using Abbott's formula, on D15 in the reference item group was 100.0%.
The emergence of adults (emergence rate) at the end of the test (on D22) in the control group was 86.1%. In the groups treated with the test item at the cumulative dose of 100.0 µg test item/larva the adult emergence rates were: 88.9%, respectively.
The endpoint values for Mezot 100 SC at the end of the assessment (D22):
- ED50 value is higher than 100.0 µg test item/larva,
- EC50 value is higher than 649.4 mg/kg,
- NOED value is higher than or equal to 100.0 µg test item/larva,
- NOEC value is higher than or equal to 649.4 mg/kg.

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

No additional studies submitted.

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

No additional studies submitted.

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

No additional studies submitted.

A 2.3.2. KCP 10.3.2 Effects on arthropods other than bees

Comments of zRMS:

The study is considered acceptable.
All validity criteria were met.
The following validity criteria were met during the test:

- mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%),
- mortality of the mites exposed to the reference item at the rate of 9.0 mL/ha was 96.7% on day 7 of exposure (criterion: from 50 to 100%),
- the mean number of eggs per female in the control group was 5.1 (required: ≥ 4 eggs per female).

Deviation from the study: During the definitive test there were short-term (below one hour) deviation in the relative air humidity, which was below range from SOP/B/23 and method IOBC, BART, and EPPO Joint Initiative (Blümel S. *et al.*, 2000). It did not affect the results obtained in the study. According to the Study Plan B/29/19 the study should be completed in October 2019, but it was completed in November 2019, which had no impact on the final results of the study.

Agreed endpoints:

Study group [application rate]	Parameter (endpoint)					
	Mortality		Reproduction			
Test item rate [L/ha]	Total [%]	LR_{50} [L/ha]	Test item rate [L/ha]	Mean number of eggs/ female (Rr) [no.]	Repro-duction reduction Pr [%]	ER_{50} [L/ha]
Control (0.0)	0.0	1.19 (0.91 – 1.82)**	Control (0.0)	5.1	–	0.40 (nd.)**
0.19*	10.0		0.19	3.8	26.0	
0.38*	16.7		0.38*	2.9	43.8	
0.75*	38.3		0.75*	0.9	83.0	
1.5*	56.7					
$NOER_{mortality}$: < 0.19 [L/ha]			$NOER_{reproduction}$: < 0.19 [L/ha]			

Reference item: Bi 58 Top 400 EC	
Reference item [mL/ha]	9.0
Active ingredient dimethoate [g/ha]	3.6
Mortality	
Total [%]	96.7

*: statistically significant differences between control and groups exposed to test item; ToxRat Professional 3.3.0. software [12], [SOP/B/67]
**: the LR_{50} value (with 95% limits) [SOP/B/67]
nd. : not determined

Report:	**10.3.2/01, Monika Stalmach, 2019**
Title:	A laboratory test for evaluating the effects of Mezot 100 SC on the predatory mite, Typhlodromus pyri (Sch.).
Document No:	B/29/19
Guidelines:	ESCORT

GLP	YES

SUMMARY:
The aim of the laboratory test was to evaluate the effects of the test item, Mezot 100 SC on mortality and reproduction of the predatory mite, T. pyri (Sch.).
On the basis of the preliminary test results, it was decided to use four rates of the test item in the definitive test. These were 0.19, 0.38, 0.75 and 1.5 L/ha.
The mites, T. pyri at the protonymphal stage (24 hours old) were exposed to the test item applied to plastic discs. The mites were fed with pine pollen (Pinus sp.). Mortality observations were made after 7 days of the treatment. Observations of reproduction of the control group and groups treated with the test item at rates 0.19, 0.38 and 0.75 L/ha were made after 8, 11, and 14 days of the treatment.
Mortality of T. pyri after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment were test endpoints.
To verify the sensitivity of the mites and the precision of the test procedure, an insecticide, Bi 58 Top 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 9.0 mL/ha (3.6 g a.i./ha). The control group was treated with distilled water.
Materials and methods:
Test item:
Mezot 100 SC; Content of active ingredient:
- Mesotrion : 106.6 g/L (CAS No.: 104206-82-8)
batch no.: 190521; production date: 21.05.2019
Biological test system:
the predatory mite, Typhlodromus pyri (Sch.) (Acari: Phytoseiidae)
– age:
24-hour-old protonymphs
– source:
a laboratory culture at the Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was augmented by Bias Labs Ltd. (London, UK)
Experimental design:
6 study groups:
- a control group (0.0 L/ha)
- Mezot 100 SC at rates:
- 0.19 L/ha
- 0.38 L/ha
- 0.75 L/ha
- 1.5 L/ha
- Reference item: Bi 58 Top 400 EC at the rate of 9.0 mL/ha
number of replicates: 3;
number of mites in each replicate: 20
Test conditions:
– temperature:
24 – 28°C
–relative air humidity:
57 – 85%
– photoperiod:
16 h light : 8 h dark
– light intensity:
950 lux
Statistical analysis:
Probit analysis using max. likelihood regression, Step-down Cochran-Armitage Test Procedure, Shapiro Wilk's Test on Normal Distribution, Levene's Test, Williams Multiple Sequential t-test Procedure
Endpoints:
– mite mortality after 7 days of the treatment
– LR50 and NOERmortality

– reproduction reduction (Pr) after 14 days of the treatment
– ER50 and NOERreproduction

Results:

In the definitive test, mortality of the control group after 7 days of exposure was 0.0%. After 7 days of exposure to Mezot 100 SC at rates of 0.19, 0.38, 0.75 and 1.5 L/ha, the percentages of T. pyri, mortality, after Abbott's correction, were 10.0, 16.7, 38.3 and 56.7%, respectively.

There were statistically significant differences in mortality between group treated with the test item at the rates of 0.19, 0.38, 0.75 and 1.5 L/ha and the control group (Step-down Cochran-Armitage Test Procedure, p(trend>α)).

On the basis of the obtained mortality results the LR50 is 1.19 L/ha of Mezot 100 SC. The NOERmortality is lower than 0.19 L/ha of Mezot 100 SC.

After 7 days of exposure to Bi 58 Top 400 EC at the rate of 9.0 mL/ha mortality of the mites was 96.7%. Therefore, the validity criterion specified in the Method description was met. The results obtained in the reference item group showed that the test organisms were sensitive to dimethoate.

The mean reproduction rate (Rr) in the control group was 5.1 eggs/female. The mean Rr after 14 days of exposure to Mezot 100 SC at rates 0.19, 0.38 and 0.75 L/ha were 3.8, 2.9 and 0.9 eggs/female, respectively. The percentages of reproduction reduction (Pr) caused by test item at the rates of 0.19, 0.38 and 0.75 L/ha were 26.0, 43.8 and 83.0%, respectively.

There were revealed no statistically significant differences in reproduction between the group treated with the test item at the rate of 0.19 L/ha and the control group. There were statistically significant differences between the groups treated with the test item at the rates of 0.38 and 0.75 L/ha and the control group (Williams Multiple Sequential t-test Procedure, |t|>|t*|).

On the basis of the obtained reproduction results, the ER50 is 0.40 L/ha of Mezot 100 SC/ha. The $NOER_{reproduction}$ is 0.19 L/ha of Mezot 100 SC.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. **The following validity criteria were met during the test:** – after 48 hours mortality of the control group was 0.0% (criterion: a maximum of 13.0%), – after 24 hours mortality of the group treated with the reference item at the rate of 0.12 mL/ha was 90.0% (criterion: from 75 to 100%), – the mean number of mummies per female in the control group was 8.7 (criterion: a minimum of 5.0 mummies/female), – all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring). **Deviation from the study:** The study was conducted according to the ESCORT 1 [1] and the ESCORT 2 [2] guidance documents, the guidelines developed by the IOBC, BART, and EPPO Joint Initiative [4], the Standard Operating Procedure SOP/B/25: 'A laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani-Perez)', other references given in section 9, the SOP's listed in section 10 of the report and the Study. In the definitive test, relative air humidity was lower than recommended in the Guideline range of 60 - 90 %. This short term deviation did not have an impact on the results of the definitve test. **Agreed endpoints:**

Study group [application rate]	Parameter (endpoint)					
	Mortality after 48 h of exposure		Fecundity			
Test item [L/ha]	Mortality [%]	LR_{50} Test item [L/ha]	Test item [L/ha]	Mean no. of mummies/ female	Fecundity reduction Pr [%]	ER_{50} Test item [L/ha]
Control (0.0)	0.0	–	Control (0.0)	8.7	–	–
0.35+	12.5	0.97* (0.78 – 1.27)	0.35	7.5	13.7	1.27* (0.17 – 8.44)
0.75+	37.5		0.75+	5.9	32.8	
1.5+	70.0		–	–	–	
$NOER_{mortality}$		<0.35	$NOER_{fecundity}$			0.35
Reference item: Bi 58 Top 400 EC						
Reference item [mL/ha]		0.12				
Active ingredient [g/ha]		0.048				
Mortality after 24 h of exposure						
Total [%]						
90.0						

*: the LR_{50} value (with 95% confidence limits), [SOP/B/67]
+: statisticaly significant differences [11]

Report:	**10.3.2/02, Monika Stalmach, 2019**
Title:	A laboratory test for evaluating the effects of Mezot 100 SC on the parasitic wasp, Aphidius rhopalosiphi (De Stefani-Perez).
Document No:	B/30/19
Guidelines:	ESCORT
GLP	YES

SUMMARY:
The laboratory test involved the evaluation of the effects of the test item, Mezot 100 SC on mortality and fecundity of the parasitic wasp, Aphidius rhopalosiphi. On the basis of the results of the preliminary test and consultations with the Sponsor, the definitive test was performed on three rates of the test item. These were: 0.35, 0.75 and 1.5 L Mezot 100 SC /ha. Adult wasps were exposed to the test item applied to glass plates. Mortality assessments were made 2, 24, and 48 hours after the introduction of the wasps to the test arenas.
Then, females which survived 48-hour exposure to Mezot 100 SC at tested rates i.e. 0.35 and 0.75 L/ha and the ones from the control group were subjected to fecundity assessment. To allow the oviposition, fifteen female wasps from the groups treated with Mezot 100 SC at the rates of 0.35 and 0.75 L/ha and the control group were individually introduced into fecundity units containing barley plants infested with the aphid, Rhopalosiphum padi. After the 24-hour oviposition, the wasps were removed from the test arenas. After 12 days, the number of mummies (parasitized aphids in which wasp pupae were developing) was recorded.
Mortality of the wasps after 48 hours of exposure and the percentage of fecundity reduction (Pr) 12 days after the oviposition were the endpoints.
To verify the sensitivity of the test system and the precision of the test procedure, an insecticide, i.e. Bi 58 Top 400 EC (400 g dimethoate/L) was used as a reference item. The rate of the reference item was 0.12 mL/ha (0.048 g dimethoate/ha). The control group was treated with distilled water.
Materials and methods:
Test item:

name: Mezot 100 SC; active substance: 106.6 g/L of Mesotrione; batch number: 190521; production date: 21.05.2019
Biological test system:
the parasitic wasp, Aphidius rhopalosiphi (De Stefani-Perez); Hymenoptera: Braconidae, Aphiidinae
– age:
adult females (24 - 48 hours after emerging from mummies)
– source:
a laboratory-bred culture at the Institute of Industrial Organic Chemistry, Branch Pszczyna; the culture was obtained from Bias Labs (UK).
Experimental design:
5 study groups:
– a control group (0.0 L/ha)
– Mezot 100 SC at the rate of 0.35 L/ha,
– Mezot 100 SC at the rate of 0.75 L/ha,
– Mezot 100 SC at the rate of 1.5 L/ha,
– Bi 58 Top 400 EC at the rate of 0.12 mL/ha (0.048 g a.i./ha)
mortality assessment: 4 replicates/group; 10 females/replicate
fecundity assessment: 15 replicates/group; 1 females/replicate.
Test conditions:
– temperature:
18 – 20°C
– relative air humidity:
57 – 72%
– photoperiod:
16 hours light (mortality assessment and oviposition: 1159 lx; fecundity assessment: 4970) : 8 hours dark
Results:
The effects of the test item Mezot 100 SC at the rates of 0.35, 0.75 and 1.5 L Mezot 100 SC /ha on mortality and fecundity of Aphidius rhopalosiphi.
Based on the above test results, it can be concluded that Mezot 100 SC at the rates of 0.35, 0.75 and 1.5 L Mezot 100 SC/ha had an adverse effects on mortality of Aphidius rhopalosiphi. Mezot 100 SC at the rate of 0.75 L Mezot 100 SC/ha had adverse effects on fecundity of *Aphidius rhopalosiphi*.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

No additional studies submitted.

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. The following validity criteria were met during the test: ➢ each replicate produced from 58 to 99 juveniles (79.9 mean) at the end of the experiment (criterion: ≥ 30 juveniles by the end of the experiment), ➢ the coefficient of variation of reproduction was 18.6% (criterion: ≤ 30%), ➢ adult mortality over the initial 4 weeks of the experiment was 0.0% (criterion: ≤ 10%). **Deviation from the study:** none **Agreed endpoints:**

Parameter	Value [mg test item/kg dry weight of artificial soil]	Value [mg of mesotrione artificial soil]
EC_{10}	57.5 (24.7 – 94.2)	5.60 (2.40 – 9.16)
EC_{20}	173.5 (109.6 – 240.8)	16.87 (10.66 – 23.42)
EC_{50}	>1000	>97.24
NOEC (reproduction)	56	5.45
LOEC (reproduction)	100	9.72
LC_{50}	>1000	>97.24
NOEC (survival)	18	1.75
LOEC (survival)	32	3.11

Report:	**10.4.1.1/01, Paweł Pieczka, 2020**
Title:	Mezot 100 SC Earthworm Reproduction Test (Eisenia andrei)
Document No:	G/64/19
Guidelines:	OECD 222
GLP	YES

Test item: Mezot 100 SC, batch number: 190521.
Artificial soil: 10 % sphagnum peat, 20% kaolin clay, 70 % sand
Test organism: the earthworm, *Eisenia andrei* obtained from a standard laboratory culture
Test design:
test duration: 8 weeks; number of replicates: 4 replicates/concentration
+ 8 replicates/control; number of earthworms: 10 earthworms/replicate
Concentrations of the test item: control, 5.6, 10.0, 18.0, 32.0, 56.0, 100.0, 180.0, 320.0, 560.0, and 1000.0 mg/kg dry weight of the artificial soil
Test conditions: temperature: 19,8 – 22 °C; pH at the beginning of the experiment: 5,50 – 5,58; pH at the end of the experiment: 5,37 – 5,73; soil moisture content at the beginning of the experiment: 26 – 29,2 % (51 – 57,4 % of the maximum water holding capacity); soil moisture content at the end of the experiment: 23,9 – 29,4 % (46,9 – 57,8 % of the maximum water holding capacity); light-dark cycle: 16 h : 8 h; light intensity at the beginning of the experiment: 466.6 – 744.2 lux; light intensity at the end of the experiment: 682.3 – 717.8 lux.
Results:
At concentrations ranging from 5.6 to 1000.0 mg of the test item/kg dry weight of artificial soil, after 4 weeks of exposure to the test item, mortality of the adult earthworms was between 0.0 and 37.5%.
As for the control group, no mortality was observed.
The concentration of the test item causing 50% mortality of the adult earthworms (LC50) is above 1000 mg/kg dry weight of artificial soil (97.24 mg of mesotrione / kg dry weight of artificial soil).
Among the changes in the appearance (morphology) and behaviour of the living earthworms the corpus narrowing and inactive earthworms were noticed.
After the application of the test item at the concentrations ranging from 5.6 to 32.0 mg/kg dry weight of

artificial soil, the body weight increase was between 0.4 and 9.2%. At the concentrations ranging from 56 to 1000 mg/kg dry weight of artificial soil, the body weight decrease was between 9.0 to 27.1%. As for the control group, the body weight increase was equal to 8.3%.
After 8 weeks of the experiment, the obtained results led to the following conclusions:
After the application of the test item at the concentrations ranging from 5.6 to 1000.0 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 82.3 – 44.8 per replicate. The mean number of juveniles in the control group was equal to 79.9 per replicate.
After 8 weeks of the experiment, it was concluded that MEZOT 100 SC had a statistically significant impact on reproduction of the earthworms at the concentrations ranging from 100 to 1000.0 mg/kg dry weight of the artificial soil.
The endpoint values showing the impact of the test item on reproduction and survival of adult earthworms are presented in the table given below:

Parameter	**Value [mg test item/kg dry weight of artificial soil]**	**Value [mg of mesotrione artificial soil]**
EC10	57.5 (24.7 – 94.2)	5.60 (2.40 – 9.16)
EC20	173.5 (109.6 – 240.8)	16.87 (10.66 – 23.42)
EC50	>1000	>97.24
NOEC (reproduction)	56	5.45
LOEC (reproduction)	100	9.72
LC50	>1000	>97.24
NOEC (survival)	18	1.75
LOEC (survival)	32	3.11

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

No studies submitted.

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

No studies submitted.

A 2.4.2.1 KCP 10.4.2.1 Species level testing

No studies submitted.

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

No studies submitted.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:

The study is considered acceptable.
All validity criteria were met.
The following validity criteria were met during the test:
The coefficients of variation (CV) in the control group were 7.6, 4.5, 3.5 and 3.4%, after 0, 7, 14 and 28 days of incubation. The validity criterion was met, because the variation between replicate control samples is less than ± 15%.
Deviation from the study: According the Guideline, the soil extraction should be conducted at 150 rpm for 60 min. However, in this study, the extraction was performed at 90 rpm for 24 hours. The modification resulted from the optimization of the nitrate extraction which showed that the extraction was more effective when the shaking rate was lower and the extraction lasted longer.
These deviation did not affect the results of the study.
Agreed endpoints:

Nitrate formation rate* [mg nitrate/kg dry weight of soil/day] for selected time intervals.

Time interval [d]	Control				PEC				5 x PEC			
	Replicate			Mean ± SD	Replicate			Mean ± SD	Replicate			Mean ± SD
	I	II	III		I	II	III		I	II	III	
0 – 7	16.604	15.783	17.911	16.766 ± 1.07	15.752	17.338	18.602	17.230 ± 1.43	18.197	18.790	20.297	19.095 ± 1.08
0 – 14	14.223	15.251	14.101	14.525 ± 0.63	15.218	15.753	15.471	15.481 ± 0.27	15.894	14.326	15.655	15.292 ± 0.84
0 – 28	6.453	6.794	7.029	6.758 ± 0.29	5.720	6.648	6.443	6.270 ± 0.49	7.051	6.820	6.888	6.920 ± 0.12

* - Rate of nitrate ions formation per a day = [(mg nitrate / kg of soil dry weight on sampling day 'a') - (mg nitrate / kg of soil dry weight on day 0)]/ 'a' day; 'a' = 7, 14 and 28 day

The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC: 1.64 mg of the test item/kg dry weight of soil (0.16 mg of mesotrione/kg dry weight of soil) and 5xPEC: 8.22 mg of the test item/kg dry weight of soil (0.80 mg of mesotrione/kg dry weight of soil) did not exceed 25% on 28 day of analysis.

Report:	**10.5/01, Paweł Pieczka, 2020**
Title:	Mezot 100 SC Soil Microorganisms: Nitrogen Transformation Test
Document No:	G/65/19
Guidelines:	OECD 216
GLP	YES

Test item: Mezot 100 SC, batch number: 190521
Soil: agricultural
Test design: three portions of soil (3 x 1500 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 500 g). Test duration: 28 days.
Concentrations of the test material: Control; PEC: 1,64 mg/kg soil and 5 x PEC: 8,22 mg/kg soil
Test conditions: Temperature: 19,9 – 21,8 °C, soil moisture: 51,4 – 57,5 % of the maximum water holding capacity, incubation in darkness.
Results :

The difference in the nitrate formation rate between the control soil and the one treated with the test item at the concentrations corresponding to the PEC: 1.64 mg of the test item / kg dry weight of soil (0.16 mg of mesotrione/kg dry weight of soil) and 5xPEC: 8.22 mg of the test item / kg dry weight of soil (0.80 mg of mesotrione/kg dry weight of soil) did not exceed 25% on 28 day of analysis.

Conclusions:

On the basis of the results, it was concluded that MEZOT 100 SC at the concentrations corresponding to the PEC: 1.64 mg of the test item / kg dry weight of soil (0.16 mg of mesotrione/kg dry weight of soil) and 5xPEC: 8.22 mg of the test item / kg dry weight of soil (0.80 mg of mesotrione/kg dry weight of soil) did not have any long-term adverse effects on the process of nitrogen transformation in aerobic surface soils.

Comments of zRMS:

The study is considered acceptable.
All validity criteria were met.
The following validity criteria were met during the test:
- the seedling emergence in the control (validity criterion: at least 70%) was as follows:
100.0% – pea,
100.0% – sunflower,
100.0% – cabbage,
95.0% – carrot,
100.0% – perennial ryegrass,
100.0% – oats,
- the mean survival of the emerged control seedlings was 100% for pea, sunflower, cabbage, carrot, perennial ryegrass and oats (validity criterion: at least 90%);
- the control seedlings did not exhibit any visible phytotoxic effects;
- environmental conditions for all plants of the same species were identical.

Deviation from the study: According to OECD Guideline No. 208 (2006), the light intensity should be 350±50µE/m^2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 52.9 and 167.4 µE/m^2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing.
This deviation did not affect results of the experiment.

Agreed endpoints:

Toxicity endpoints expressed as mL of the test item/ha

	Pea *Pisum sativum*	Sunflower *Helianthus annuus*	Cabbage *Brassica oleracea var. capitata*	Carrot *Daucus carota*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	>1500	>1500	1454.4 (910.0 ->1500.0)	286.5	>1500	>1500
NOER	≥1500	≥1500	166.7	55.6	≥1500	≥1500
Shoot length (plants without roots)						
ER_{50}	200.8 (138.9 – 302.7)	940.6 (835.7 – 1072.3)	96.2 (44.1 – 199.8)	515.2 (494.2 – 538.0)	>1500	>1500
NOER	6.2	55.6	6.2	18.5	≥1500	500.0
Plant dry weight (plants without roots)						
ER_{50}	95.5 (54.3 – 178.0)	137.9 (74.3 – 261.9)	80.9 (49.1 – 133.2)	89.6 (68.0 – 120.7)	>1500	>1500
NOER	2.1	18.5	6.2	2.1	500.0	500.0

Toxicity endpoints expressed as g of mesotrione/ha

	Pea *Pisum sativum*	Sunflower *Helianthus annuus*	Cabbage *Brassica oleracea var. capitata*	Carrot *Daucus carota*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	>159.9	>159.9	155.0 (97.0 ->159.9)	30.5	>159.9	>159.9
NOER	≥159.9	≥159.9	17.8	5.9	≥159.9	≥159.9
Shoot length (plants without roots)						
ER_{50}	21.4 (14.8 – 32.3)	100.3 (89.1 – 114.3)	10.3 (4.7 – 21.3)	54.9 (52.7 – 57.4)	>159.9	>159.9
NOER	0.7	5.9	0.7	2.0	≥159.9	53.3
Plant dry weight (plants without roots)						
ER_{50}	10.2 (5.8 – 19.0)	14.7 (7.9 – 27.9)	8.6 (5.2 – 14.2)	9.6 (7.3 – 12.9)	>159.9	>159.9
NOER	0.2	2.0	0.7	0.2	53.3	53.3

Agreed toxicity endpoints based on phytotoxicity effect:

ER_{50} values determined on the basis of plant damages at the end of the exposure.

Plant damages at the end of the exposure						
	Pea *Pisum sativum*	**Sunflower** *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
mL of the test item/ha						
ER_{50}	239.6 (181.0 – 317.2)	323.5 (259.8 – 402.7)	102.0 (89.1 – 116.8)	178.6 (159.9 – 199.5)	> 1500.0	> 1500.0
g of the mesotrione/ha						
ER_{50}	25.5 (19.3 – 33.8)	34.5 (27.7 – 42.9)	10.9 (9.5 – 12.5)	19.0 (17.0 – 21.3)	> 159.9	> 159.9

ER_{50} values were calculated using ToxRatPro Version 3.3.0.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

Report:	**10.6/01, Magdalena Wołany, 2020**
Title:	Mezot 100 SC Terrestial Plant Test: Seedling Emergence and Seedling Growth Test
Document No:	G/62/19
Guidelines:	OECD 208
GLP	YES

SUMMARY:
The study, aimed at evaluating the effect of MEZOT 100 SC on seedling emergence and seedling growth of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. The test item was sprayed onto the soil surface. For each species, eight application rates were used. There was also a

concurrent control group. Seeds of the test plant species were sown in plastic pots. There were 3 (pea, cabbage, sunflower) or 5 (carrot, perennial ryegrass, oats) seeds/pot. The experiment was conducted in a special room. Suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for emergence (every day and then every 2 – 3 days) and visual phytotoxicity (after 7 and 14 days). The experiment finished 14 days after the emergence of 50% of the control seedlings. At the end of the experiment, the number of surviving plants was determined. Next, the plants were cut down, measured, dried to a constant weight at 60ºC, and weighed.
The results concerning the emergence, the shoot length, and the dry weight were statistically analyzed in order to determine the ER25, ER50, and NOER.
Materials and methods:
Test item:
MEZOT 100 SC
batch number: 190521
active substance: mesotrione: 106.6 g/L (Appendix No. 1)
Test species:
pea (Pisum sativum), sunflower (Helianthus annuus), cabbage (Brassica oleracea var. capitata), carrot (Daucus carota), perennial ryegrass (Lolium perenne), oats (Avena sativa).
Soil:
Sandy loam
Study design:
number of rates: 8 + control; number of replicates/rate: 4 (carrot, perennial ryegrass, oats) or 7 (pea, sunflower, cabbage). The total number of seeds per application rate – 20 (carrot, perennial ryegrass, oats) or 21 (sunflower, cabbage, pea).
test termination: 14 days after the emergence of 50% of the control seedlings
Application rates:
a control, 0.7, 2.1, 6.2, 18.5, 55.6, 166.7, 500.0 and 1500.0 mL test item/ha,
volume of deionized water used to prepare the highest rate corresponded 300 L water/ha
Test conditions:
temperature: 18.8 – 25.3°C, humidity: 45.1 – 92.4%, lighting: 16 h light : 8 h dark; light intensity: 52.9 – 167.4 µE/m2/s; carbon dioxide concentration: 348 – 385 ppm

Results expressed as g of mesotrione/ha:

Species	**Substance**	**Exposure System**	**Results ER_{50} [g/ha]**
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*.	Mesotrione (Mezot 100 SC)	Seedling emergence: Plant number at the end of the experiment	159,9 159,9 155,0 30,5 159,9 159,9
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*.		Seedling emergence: Shoot length (plants without roots)	21,4 100,3 10,3 54,9 159,9 159,9
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*.		Seedling emergence: Plant dry weight (plants without roots)	10,2 14,7 8,6 9,6 159,9 159,9

Amendment:

The ER50 values based on percentage plant damages at the end of the exposure were determined using statistical tests, i.e. Probit analysis using linear max. likelihood regression. The ToxRatPro Version 3.3.0 computer software was used.
The amendment to the final report supplements the results of the experiment with a statistical analysis of phytotoxic symptoms observed on the tested plant species at the end of exposure. Therefore, the description of the results is completed with an information on the numbering of the rate - effect curves showing the influence of the test item on the percentage of phytotoxic symptoms.

The ER50 values determined on the basis of plant damages at the end of the exposure are presented in the table:

Plant damages at the end of the exposure						
	Pea Pisum sativum	**Sunflower** Helianthus annuus	**Cabbage** Brassica oleracea var. capitata	**Carrot** Daucus carota	**Perennial ryegrass** Lolium perenne	**Oats** Avena sativa
mL of the test item/ha						
ER50	239.6 (181.0 – 317.2)	323.5 (259.8 – 402.7)	102.0 (89.1 – 116.8)	178.6 (159.9 – 199.5)	> 1500.0	> 1500.0
g of the mesotrione/ha						
ER50	25.5 (19.3 – 33.8)	34.5 (27.7 – 42.9)	10.9 (9.5 – 12.5)	19.0 (17.0 – 21.3)	> 159.9	> 159.9

Comments of zRMS:	The study is considered acceptable. All validity criteria were met. The following validity criteria were met during the test: - the seedling emergence of plants (validity criterion: at least 70%) was as follows: 73.8 – 88.1– sunflower, 88.1 – 95.2 – cabbage, 73.8 – 85.7 – pea, 75.0 – 95.0 – carrot, 77.5 – 97.5 – perennial ryegrass, 75.0 – 87.5 – oats, - the mean plant survival of the control was 100% for all tested species (validity criterion: at least 90%), - the control plants did not exhibit any visible phytotoxic symptoms, - environmental conditions for all plants belonging to the same species were identical. **Deviation from the study:** According to OECD Guideline No. 227 (2006), the light intensity should be 350 ± 50µE/m2/s. However, these values are recommended for tests conducted in greenhouses. The experiment was conducted in a test room, where only artificial lighting was used. The light intensity was between 78.3 and 182.3 µE/m2/s. Good control plant vigour was observed. Therefore, it was concluded that the light intensity was suitable for plant growing. All above mentioned deviations did not affect the results of the study. **Agreed endpoints:**

Toxicity endpoints expressed as mL of the test item/ha

	Sunflower *Helianthus annuus*	Cabbage *Brassica oleracea var. capitata*	Pea *Pisum sativum*	Carrot *Daucus carota*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 1500.00	> 1500.00	> 1500.00	> 1500.0	> 1500.00	> 1500.00
NOER	≥ 1500.00	≥ 1500.00	≥ 1500.00	500.0	≥ 1500.00	≥ 1500.00
Shoot length (plants without roots)						
ER_{50}	127.97 (70.98 – 249.53)	313.76 (221.21 – 471.45)	46.58	146.05	> 1500.00	> 1500.00
NOER	2.10	0.70	18.50	18.50	500.00	55.60
Plant dry weight (plants without roots)						
ER_{50}	14.52	23.41	47.87 (8.95 – 167.58)	72.48 (58.87 – 89.31)	1437.69	926.54
NOER	6.20	2.10	6.20	18.50	500.00	55.60

Toxicity endpoints expressed as g of mesotrione/ha

	Sunflower *Helianthus annuus*	Cabbage *Brassica oleracea var. capitata*	Pea *Pisum sativum*	Carrot *Daucus carota*	Perennial ryegrass *Lolium perenne*	Oats *Avena sativa*
Plant number at the end of the experiment						
ER_{50}	> 159.90	> 159.90	> 159.90	> 1500.0	> 159.90	> 159.90
NOER	≥ 159.90	≥ 159.90	≥ 159.90	53.30	≥ 159.90	≥ 159.90
Shoot length (plants without roots)						
ER_{50}	13.64 (7.57 – 26.60)	33.45 (23.58 – 50.26)	4.97	15.57	> 159.90	> 159.90
NOER	0.22	0.07	1.97	1.97	53.30	5.93
Plant dry weight (plants without roots)						
ER_{50}	1.55	2.49	5.10 (0.95 – 17.86)	7.73 (6.28 – 9.52)	153.26	98.77
NOER	0.66	0.22	0.66	1.97	53.30	5.93

Agreed toxicity endpoints based on phytotoxicity effect:

ER_{50} values determined on the basis of plant damages at the end of the exposure

Plant damage at the end of the exposure						
	Sunflower *Helianthus annuus*	**Cabbage** *Brassica oleracea var. capitata*	**Pea** *Pisum sativum*	**Carrot** *Daucus carota*	**Perennial ryegrass** *Lolium perenne*	**Oats** *Avena sativa*
mL of the test item/ha						
ER_{50}	51.50 (27.74 – 95.60)	67.78 (45.16 – 101.73)	57.81 (34.29 – 97.45)	109.13 (75.55 – 157.64)	1264.84 (1247.93 – 1282.01)	1162.66 (993.69 – 1360.36)
g of mesotrione/ha						
ER_{50}	5.49 (2.96 – 10.19)	7.26 (4.81 – 10.85)	6.16 (3.66 – 10.39)	11.63 (8.05 – 16.81)	134.83 (133.03 – 136.66)	123.94 (105.93 – 145.01)

ER_{50} values were calculated using ToxRatPro Version 3.3.0.

Report:	**10.6/02, Patrycja Holewik, 2020**
Title:	Mezot 100 SC Terrestial Plant Test: Vegetative Vigour Test
Document No:	G/63/19
Guidelines:	OECD 227
GLP	YES

SUMMARY:
The study, aimed at evaluating the effect of MEZOT 100 SC on vegetative vigour of 6 terrestrial plants, was conducted on 4 dicotyledonous and 2 monocotyledonous species. Seeds of the test plant species were sown in plastic pots (10 seeds/pot for carrot, perennial ryegrass, oats and 6 seeds/pot for sunflower, cabbage, pea). The plants were grown to the 2- to 4- true leaf stage. Then, some of them were removed. As a result, the number of plants per pot as well as the total number of plants per concentration were:
- sunflower: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- cabbage: 3 plants/pot – 21 plants/ application rate (7 pots/ application rate);
- pea: 3 plants/pot – 21 plants/application rate (7 pots/application rate);
- carrot: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- perennial ryegrass: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate);
- oats: 5 plants/pot – 20 plants/ application rate (4 pots/ application rate).

The pot is defined as a replicate. The test item was sprayed onto the plants. For each species, eight application rates were used. Untreated control group was conducted simultaneously. The treated and the control groups were divided into four replicates for carrot, perennial ryegrass, oats and 7 replicates for sunflower, cabbage, pea. The experiment was conducted in a plant growth room where suitable environmental conditions for each test species were provided. During the experiment, the plants were observed for visual phytotoxicity (7, 14 and 21 days after the test item application). The experiment finished 21 days after the spraying. At the end of the experiment, the number of surviving plants was counted. Next, the plants were cut down, and the lengths of their shoots were determined. Finally, they were dried at 60ºC to a constant weight and weighed.
The results concerning the shoot length, the dry weight, and the number of plants at the end of the experiment were statistically analyzed to determine the ER25, ER50 and NOER.
Materials and methods:
Test item:
MEZOT 100 SC
batch number: 190521
active substances: mesotrione: 106.6 g/L (Appendix No. 1)
Test species:
pea (Pisum sativum), cabbage (Brassica oleracea var. capitata), carrot (Daucus carota), sunflower (Helianthus annuus), perennial ryegrass (Lolium perenne), oats (Avena sativa).
Soil:
Sandy loam
Study design:
number of rates: 8 + control; number of replicates/rate: 4 (carrot, perennial ryegrass, oats) or 7 (sunflower, cabbage, pea). The total number of plants per application rate – 20 (carrot, perennial ryegrass, oats) or 21 (cabbage, pea, sunflower),
test termination: 21 days after the spraying
Application rates:
a control, 0.7, 2.1, 6.2, 18.5, 55.6, 166.7, 500.0 and 1500.0 mL test item/ha, volume of deionized water used to prepare the highest rate corresponded to 300 L water/ha
Test conditions:

temperature: 18.8 – 25.3°C, humidity: 45.1 – 92.4%, lighting: 16 h light : 8 h dark; light intensity: 78.3 – 182.3 µE/m2/s; carbon dioxide concentration: 320 – 366 ppm.

Results expressed as g of mesotrione/ha:

Species	Substance	Exposure System	Results ER_{50} [g/ha]
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*.	Mesotrione (Mezot 100 SC)	Vegetative vigour: Plant number at the end of the experiment	159,9 159,9 159,9 159,9 159,9 159,9
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*.		Vegetative vigour: Shoot length (plants without roots)	13,64 33,45 4,97 15,57 159,9 159,9
pea *(Pisum sativum)*, sunflower *(Helianthus annuus)*, cabbage *(Brassica oleracea var. capitata)*, carrot *(Daucus carota)*, perennial ryegrass *(Lolium perenne)*, oats *(Avena sativa)*.		Vegetative vigour: Plant dry weight (plants without roots)	1,55 2,49 5,10 7,73 153,26 98,77

Amendment:
The ER50 values based on percentage plant damages at the end of exposure were determined using statistical tests, i.e. probit or logit analysis using linear max. likelihood regression. The ToxRatPro Version 3.3.0 computer software was used.
The Amendment No. 1 to the final report supplements the results of the experiment with a statistical analysis of phytotoxic symptoms observed on the tested plant species. Therefore, the description of the results is completed with an information on the numbering of the rate - effect curves showing the influence of the test item on the percentage of phytotoxic symptoms.
The ER50 values determined on the basis of plant damages at the end of the exposure are presented in the table:

	Plant damage at the end of the exposure					
	Sunflower Helianthus annuus	**Cabbage** Brassica oleracea var. capitata	**Pea** Pisum sativum	**Carrot** Daucus carota	**Perennial ryegrass** Lolium perenne	**Oats** Avena sativa
	mL of the test item/ha					
ER50	51.50 (27.74 – 95.60)	67.78 (45.16 – 101.73)	57.81 (34.29 – 97.45)	109.13 (75.55 – 157.64)	1264.84 (1247.93 – 1282.01)	1162.66 (993.69 – 1360.36)

	g of mesotrione/ha					
ER50	5.49 (2.96 – 10.19)	7.26 (4.81 – 10.85)	6.16 (3.66 – 10.39)	11.63 (8.05 – 16.81)	134.83 (133.03 – 136.66)	123.94 (105.93 – 145.01)

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

No studies submitted.

A 2.8 KCP 10.8 Monitoring data

No additional information.