

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: M-100SC-OR2-C

Product name(s): Juzan Extra 100 SC

Chemical active substance:

mesotrione, 100 g/l

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 05/2022

MS Finalisation date: 01/2023, 05/2023

Version history

When	What
May 2022	First submission of product authorization to Poland.
January 2023	ZRMS evaluated dRR submitted by Applicant
May 2023	The final version of RR after commenting period

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PART A

RISK MANAGEMENT

1 Details of the application

This application is submitted by company CIECH Sarzyna Spółka Akcyjna, ul Chemików 1, 37-310 Nowa Sarzyna, Poland in May 2022.

The information, data and assessments provided in Registration Report, Parts B includes assessment of data and information relating to Juzan Extra 100 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of Juzan Extra 100 SC have been made using endpoints agreed in the EU review of mesotrione.

1.1 Application background

The application is submitted for registration of plant protection product Juzan Extra 100 SC in Poland according to art. 33 of Regulation 1107/2009. The zRMS is Poland. The uses applied for is maize at BBCH growth stage of 12 – 18. The application is also submitted for the registration of minor uses i.e. sugar maize and popcorn in Poland.

1.2 Letters of Access

CIECH Sarzyna S.A. has Letters of Access to studies/data. Detailed information is included in Part C.

1.3 Justification for submission of tests and studies

All tests and studies for Juzan Extra 100 SC are submitted to meet the requirements of Regulation (EC) No. 284/2013. These studies are necessary to gain the authorisation.

1.4 Data protection claims

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

2 Details of the authorization decision

2.1 Product identity

Product code	M-100SC-OR2-C
Product name in MS	Juzan Extra 100 SC
Authorization number	First authorisation
Function	herbicide
Applicant	CIECH Sarzyna S.A.

Active substance(s) (incl. content)	mesotrione; 100 g/L
Formulation type	Suspension concentrate [Code: SC]
Packaging	<p><u>Material: HDPE</u> 250 ml; 500 mL, 1 L - bottles 3 L; 5 L; 10 L; 20 L; 60 L – canisters 120 L; 200 L – drums 1000 L – container</p> <p><u>Material: HDPE/PA</u> 250 ml; 500 mL, 1 L - bottles 2 L; 3 L; 5 L; 10 L – canisters</p> <p><u>Material: HDPE/EVOH</u> 250 ml; 500 mL, 1 L - bottles 2 L; 3 L; 5 L; 10 L; 20 L – canisters</p> <p><u>Material: HDPE/F</u> 250 ml; 500 mL, 1 L - bottles 2 L; 3 L; 5 L; 10 L; 20 L – canisters</p> <p>All for professional users</p>
Coformulants of concern for national authorizations	N/A
Restrictions related to identity	N/A
Mandatory tank mixtures	N/A
Recommended tank mixtures	N/A

2.2 Conclusion

Physical and chemical properties section:

No data gaps.

Analytical methods section:

No data gaps.

Efficacy section: Juzan Extra 100 SC can be granted in Poland for protect maize crops against weeds at dose 0.75-~~1.0~~ **1.5** L/ha. Classification of accepted list weeds is presented in Polish label project and B3. Sugar maize (ZEAMS) and popcorn (ZEAME) maize can be registered according to Article 51 (without any trial).

Mammalian toxicology:

Classification of JUZAN EXTRA 250 EC Repr.2/H361d, ~~STOT RE 2/H373~~ and Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. [EUH 208]. The risk for the operator and worker is acceptable using personal protective equipment: work wear (arms, body and legs covered) Mixing/Loading and Application + gloves, and for resident/ bystander if will be 5 meter buffer strip and the table states that residents and bystanders should not enter the treated area.

Metabolism and residues:

Uses are accepted

Ecotoxicology section:

Uses are not accepted. Applicant should submit additional refinement option.

(Justification: No safe use was concluded following application of Juzan Extra 100 EC at 1.5 L/ha (corresponding to 150 g a.s./ha) for long term risk assessment for mammals and further refinement is required.

~~The high long term drinking water risk for mammals was identified for dose rate 150 g a.s./ha using the Koc value for pH 7.8 (14 L/kg). Applicant should submit additional refinement option)~~

The National Addendum for Poland containing supplementary information with refinement risk assessment for mammals for Juzan Extra 100 EC was submitted by the Applicant.

Uses are accepted. However, it is necessary to reduce the dose in GAP to 0.100 kg s.a./ha.

(justification: based on the new f_{TWA} , application for rabbit is still unacceptable. The RMS proposes to reduce the dose to 0.100 kg s.a./ha. New calculation was provided by RMS based on reduced dose (0.100 kg s.a./ha). The trigger value for rabbit and *Apodemus sylvaticus* are above the trigger of 5. Therefore, further refinement is not required for this species as the TER_{LT} is above the trigger of 5 indicating acceptable risk to mammals.

Juzan Extra 100 SC pose no unacceptable risk to aquatic organisms according to the label with appropriate buffer zone: 20 m vegetative buffer zone (the worst case scenario – R1 stream – pH 5.1).

To protect non-target plants respect an unsprayed buffer zone of 10 m or 5 m with 50% drift reduction or 1 m with 90% drift reduction to non-agricultural land.

2.3 Substances of concern for national monitoring

National monitoring data is not available.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Repr. 2 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS08 GHS09
Signal word:	Warning
Hazard statement(s):	H361d -Suspected of damaging the unborn child H373-May cause damage to organs through prolonged or repeated exposure (eye and nerves system) H400 – Very toxic to aquatic life. H410 – Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P280 Wear protective gloves/ protective clothing P308 + P313 IF exposed or concerned: Get medical advice/attention P314-Get medical advice/attention if you feel unwell P391 Collect spillage P405 Store locked up P501 - Dispose of contents/container in accordance to national regulations.

Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. [EUH 208]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. [EUH 208]

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect non-target plants respect an unsprayed 1 m buffer zone to non-agricultural land together with 90% drift reduction or 5 m buffer zone to non-agricultural land together with 50% drift reduction or 10 m buffer zone to non-agricultural land with no drift reduction.
SPe3	To protect aquatic organisms 20 meter vegetative buffer zone surface water bodies.

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

	N/A
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2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
respective code if available	Workwear and gloves during mixing/loading and application
Worker protection:	
respective code if available	Workwear and gloves when handling treated crops
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SPe1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).

SPe3	To protect non-target plants respect an unsprayed 1 m buffer zone to non-agricultural land together with 90% drift reduction or 5 m buffer zone to non-agricultural land together with 50% drift reduction or 10 m buffer zone to non-agricultural land with no drift reduction.
	To protect aquatic organisms 20 meter vegetative buffer zone surface water bodies.
Other specific restrictions	
-	-

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

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

2.5.2 Specific restrictions linked to the intended uses

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

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): **Juzan Extra 100 SC** Formulation type: Suspension concentrate (SC) ^(a,b)
Active substance 1: mesotrione Conc. of as 1: 100 g/l ^(c)
Safener: n.a Conc. of safener: n.a ^(c)
Synergist: n.a Conc. of synergist: n.a ^(c)

Applicant: CIECH Sarzyna S.A. Professional use: ☒
Zone(s): Central ^(d) Non professional use: ☐
Verified by MS: YES
Field of use: Herbicide

GAP rev. 1, date: 2022-02-14

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽ⁱ⁾
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applica- tions (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Maize (ZE-AMX)	F	Monotyledonous weeds (TTDMS); Dicotyledonous weeds (TTDSS)	spraying	BBCH 12 - 18	a) 1 b) 1	n.a.	a) 1,5 L/ha a) 1,0 L/ha b) 1,5 L/ha b) 1,0 L/ha	a) 150 g as/ha a) 100 g as/ha b) 150 g as/ha b) 100 g as/ha	200 / 400	n.a.	Dose range: 0,75-4,5 1.0 l/ha
Minor uses according to Article 51 (zonal uses)													
2	PL	sugar maize (ZEAMS);	F	Monotyledonous weeds (TTDMS);	spraying	BBCH 12 - 18	a) 1	n.a.	a) 1,5 L/ha	a) 150	200 / 400	n.a.	Dose range: 0,75-4,5 1.0 l/ha

		Popcorn (ZE- AME);		Dicotyledonous weeds (TTDSS)			b) 1		a) 1,0 L/ha b) 4,5 L/ha b) 1,0 L/ha	g-as/ha a) 100 g as/ha b) 150 g-as/ha b) 100 g as/ha			
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	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The product is homogenous light-beige liquid, with a slight characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature 530°C. In aqueous solution, it has a pH value around 3.52 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate that a shelf life of at least 2 years at ambient temperature has to be expected when stored in high density polyethylene (HDPE) bottles. Its technical characteristics are acceptable for a SC formulation. The intended concentration of use is 0.375% to 0.75%.

According to available interim report after 2-years of storage the product is stable at ambient temperature when stored in HDPE bottles.

3.2 Efficacy (Part B, Section 3)

JUZAN EXTRA 100 SC is a suspension concentration (SC) formulation containing 100 g/L mesotrione intended to give effective control of annual broad-leaved and some grass weeds in foliar post-emergence application in maize and minor crops: sugar maize and popcorn.

3.3 Efficacy data

A total of 18 trials investigating the minimum effective dose and the effectiveness of JUZAN EXTRA 100 SC against annual broadleaf and grass weeds were implemented in maize in 2016 (5 trials) and 2019 (13 trials).

Trials were located in the North-Eastern EPPO zone in Poland (6 trials), in the Maritime EPPO zone in Germany (2 trials) and Czech Republic (3 trials), and in the South-Eastern EPPO zone in Hungary (2 trials), in Romania (4 trials) and in Slovakia (1 trial).

Across these 18 trials, JUZAN EXTRA 100 SC was applied at a single timing made post-emergence of the crop (BBCH 12-18) at dose range 0,6 – 1,5 L/ha.

It has been demonstrated that the minimum effective dose of JUZAN EXTRA 100 SC applied post-emergence for the control of some dicotyledonous weeds 0,75 L/ha, when compared with lower tested rate (0,6 L/ha) for which efficacy obtained was lower and less consistent. However, 1,5 L/ha dose of JUZAN EXTRA 100 SC provided optimum overall control of most of the weed species in maize. Therefore the target doses range 0,75-~~1,5~~ 1,0 L/ha should be considered as effective against targeted weed species, for which activity of JUZAN EXTRA 100 SC is claimed. Max. accepted dose was changed due to assessment made by Ecotox section. Ecotox accepted max. 100 g.a.s./ha of mesotrione, so only max dose 1.0 L/ha can be accepted by section efficacy as it was studied during field trials.

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

The Applicant was notified that according to PP 1/226 at least 6 trials are required. For Maritime EPPO zone Applicant submitted 5 trials (DE-2, CZ-3) carried out in 2016 and 2019; for N-E EPPO zone 6 trials (PL) performed in 2016 and 2019 and for S-E EPPO zone – 7 trials (SK-1, HU-6) carried out in 2016 and

2019.

Number of trials for efficacy from North-East and South -East EPPO zone is sufficient. One study is missing for the Maritime EPPO zone - so CMS from the maritime zone should consider, ex. taking into account results from other climate zones. Lack of trials for MED zone. Sugar maize (ZEAMS) and popcorn (ZEAME) maize can be registered according to Article 51 (without any trial).

All details about efficacy methodology used during efficacy trials are presented above by Applicant. The reports include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards (1/252 (4); 1/225 (2); 1/50 (3); 1/135 (4) and 1/181 (4). Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized.

Data were presented correctly by Applicant in the tables. Results were comparable to standard reference product used during trials. All trials and weed species were characterized by sufficient level of infestation. Only trials with greater than 4 weeds/m² or over 1% ground cover have been included. For major weeds at least 4 studies should be presented and for minor- at least 2. Classification of weed species for Poland should be done according to Polish requirements. CMS should use scale of efficacy in line with its national guidelines (ex. SANCO). Applicant presented scale of weed sensitivity according to SANCO scale. However, for Poland we should use different scale: S (susceptible) > 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) < 60%.

Different varieties of maize were studied during trials. Following BBCH was studied during trials: N-E – BBCH 12-18; Maritime – BBCH 12-17 and S-E – BBCH 13-17. During all trials 200-400 L/ha water volume was studied.

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

Following weed species should be excluded from assessment and label project due to only one valid efficacy trial presented: ARBUTH (1-HU); AGREE (1-PL); AMABL (1-HU); ANGAR (1-PL); AVEFA (1-CZ); BRNN (1-DE); CIRAR (PL-1); CHEPO (1-CZ); DATST (1-SK); PANMI (1-SK); POLAM (1-HU); POLLA (1-CZ); SETVI (1-RO) and XANST (1-HU).

Below, ZRMs presented weed species for which at least 2 trials were presented:

AMARE – 7 trials: PL (2), CZ (1), HU (1), RO (3). It is a major weed in maize for Poland. Applicant submitted only 3 valid trials for PL from PL (2) and CZ (1), so number is insufficient for registration and including in Polish label. CMS from Maritime and S-E should decide if limited number of trials for AMARE can be accepted.

Efficacy for N-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	35.0%	70.6%	74.4%	76.3%	76.9%
2 nd assessment	61.3%	88.8%	91.9%	94.4%	93.8%
long term effect	68.8%	91.3%	93.8%	95.0%	95.0%

Efficacy for S-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	80.4%	85.4%	91.9%	98.4%	98.3%
2 nd assessment	80.2%	85.5%	91.8%	98.9%	98.9%
long term effect	78.2%	83.3%	90.1%	96.6%	97.0%

Efficacy for Poland (trials from PL and neighbouring countries):

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	43.8%	65.0%	68.4%	69.6%	71.3%
2 nd assessment	58.8%	78.8%	81.7%	85.4%	85.0%
long term effect	59.4%	79.6%	82.5%	85.8%	85.8%

AMBEL – 2 trials: HU (1), SK (1). It is a minor weed in maize for Poland. Applicant submitted lack of valid trials for PL, so acceptance in Polish label against AMBEL is not possible. cMS from S-E should decide if limited number of trials for AMBEL can be accepted. cMS from Maritime should decide if AMBEL can be accepted without any trial,

Efficacy for S-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	80.0%	89.0%	91.8%	93.5%	94.7%
2 nd assessment	71.3%	86.4%	88.9%	93.0%	94.3%
long term effect	no data	91.4%	92.7%	95.0%	98.0%

CHEAL – 17 trials: PL (6), DE (2), CZ (3), HU (1), RO (4), SK (1). It is a major weed in maize for Poland. Number of trials for N-E and S-E EPPO zone is sufficient. cMS from Maritime should decide if 5 trials can be accepted against CHEAL.

Efficacy for N-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	64.4%	81.7%	86.0%	88.8%	89.7%
2 nd assessment	75.6%	91.9%	95.0%	96.7%	96.7%
long term effect	66.3%	95.4%	97.1%	97.5%	97.9%

Efficacy for Maritime EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	95.1%	94.6%	97.4%	98.0%	98.0%
2 nd assessment	91.4%	98.0%	99.3%	99.5%	100%
long term effect	90.5%	97.2%	98.7%	100%	100%

Efficacy for S-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	75.0%	84.5%	91.6%	97.4%	96.6%
2 nd assessment	75.2%	84.7%	92.6%	98.0%	98.1%
long term effect	73.3%	82.4%	91.3%	97.2%	97.3%

Efficacy for Poland (trials from PL and neighbouring countries):

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	79.8%	87.3%	90.9%	92.8%	93.2%
2 nd assessment	83.5%	94.0%	96.6%	97.7%	98.1%
long term effect	83.5%	95.4%	97.5%	98.6%	98.8%

ECHCG – 15 trials: PL (6), CZ (3), HU (2), RO (3), SK (1). It is a major weed in maize for Poland. Number of trials for N-E and S-E EPPO zone is sufficient. cMS from Maritime should decide if 3 trials can be accepted against ECHCG.

Efficacy for N-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	53.8%	63.0%	70.5%	81.4%	83.4%
2 nd assessment	64.1%	69.6%	79.0%	90.5%	88.3%
long term effect	65.0%	71.7%	78.3%	88.0%	84.8%

Efficacy for Maritime EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	59.4%	77.1%	81.4%	86.7%	86.7%
2 nd assessment	68.8%	83.0%	82.0%	84.6%	87.5%
long term effect	65.7%	81.4%	80.8%	84.2%	87.5%

Efficacy for S-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	54.5%	66.4%	75.1%	85.0%	84.5%
2 nd assessment	50.0%	62.5%	73.2%	83.6%	83.5%
long term effect	49.0%	63.3%	74.1%	83.0%	82.5%

Efficacy for Poland (trials from PL and neighbouring countries):

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	55.6%	69.6%	75.7%	83.9%	84.9%
2 nd assessment	65.6%	75.3%	81.1%	89.0%	88.5%
long term effect	65.4%	77.9%	81.3%	87.2%	87.1%

GALAP – 4 trials: PL (4). It is a minor weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance GALAP in label. For Poland 4 trials are acceptable, so this weed can be included in Polish label project.

Efficacy for N-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	61.3%	70.0%	80.0%	86.5%	91.0%
2 nd assessment	60.6%	69.3%	80.5%	85.0%	89.9%
long term effect	not studied	86.3%	90.0%	91.3%	96.9%

GASPA – 3 trials: PL (2). It is a minor weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance GASPA in label. For Poland 3 trials are acceptable, so this weed can be included in Polish label project.

Efficacy for N-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	58.8%	68.3%	77.1%	79.8%	79.2%
2 nd assessment	71.1%	85.3%	93.9%	95.4%	95.1%
long term effect	68.8%	82.5%	86.3%	90.0%	90.0%

HIBTR – 4 trials: SK (1), HU (2), RO (1). It is a minor weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance HIBTR in label. For Poland registration of HIBTR on the basis on trials performed in S-E EPPO zone is not possible, this weed should be deleted from Polish label project.

Efficacy for S-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	31.9%	61.9%	66.0%	68.8%	67.8%
2 nd assessment	26.3%	57.8%	63.8%	68.1%	67.5%
long term effect	21.3%	61.3%	67.9%	72.5%	72.1%

LAMPU – 5 trials: PL (3), CZ (1), DE (1). It is a minor weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance LAMPU in label. For Poland 3 trials are acceptable, so this weed can be included in Polish label project.

Efficacy for N-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	70.0%	77.5%	89.1%	92.5%	93.5%
2 nd assessment	72.9%	90.6%	94.6%	95.2%	95.5%
long term effect	not studied	not studied	92.5%	100%	100%

Efficacy for Maritime EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	87.5%	90.1%	92.5%	99.7%	98.6%
2 nd assessment	87.5%	91.8%	93.6%	100%	98.8%
long term effect	87.5%	92.4%	93.5%	100%	98.8%

Efficacy for Poland (trials from PL and neighbouring countries):

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	75.8%	82.6%	90.5%	95.4%	95.6%
2 nd assessment	77.8%	91.1%	94.2%	97.1%	96.8%
long term effect	87.5%	92.4%	93.0%	100%	99.2%

MATCH – 2 trials: PL (1), DE (1). It is a minor weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance MATCH in label. For Poland

2 trials are acceptable, so this weed can be included in Polish label project.

Efficacy for Poland (trials from PL and neighbouring countries):

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	31.3%	33.1%	35.0%	67.4%	56.9%
2 nd assessment	38.8%	48.8%	61.9%	88.5%	79.4%
long term effect	40.0%	50.6%	58.1%	86.3%	78.1%

MATIN – 2 trials: CZ (2). It is a minor weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance MATIN in label. For Poland 2 trials are acceptable, so this weed can be included in Polish label project.

Efficacy for Maritime EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	68.8%	75.7%	83.9%	89.9%	96.8%
2 nd assessment	56.3%	73.2%	78.6%	88.9%	84.0%
long term effect	51.3%	71.9%	78.3%	86.4%	83.1%

POLAV – 4 trials: PL (3), DE (1). It is a major weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance POLAV in label. For Poland 4 trials are acceptable, so this weed can be included in Polish label project.

Efficacy for N-E:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	48.8%	68.3%	80.8%	89.2%	89.4%
2 nd assessment	38.1%	66.7%	81.3%	91.6%	92.6%
long term effect	not studied	72.5%	95.0%	98.8%	100%

Efficacy for Maritime EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	0%	0%	0%	0%	0%
2 nd assessment	0%	0%	0%	0%	0%
long term effect	0%	0%	0%	0%	0%

POLCO – 6 trials: PL (3), DE (2), CZ (1). It is a major weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance POLCO in label. For Poland 6 trials are acceptable, so this weed can be included in Polish label project.

Efficacy for N-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	50.0%	65.8%	76.7%	87.9%	87.5%
2 nd assessment	46.9%	65.8%	80.8%	92.1%	92.9%
long term effect	not studied	57.5%	78.3%	86.3%	84.5%

Efficacy for Maritime EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	61.3%	64.2%	69.6%	91.3%	88.3%
2 nd assessment	55.3%	61.7%	65.0%	85.4%	82.9%
long term effect	51.9%	59.2%	62.9%	84.6%	81.7%

Efficacy for Poland (trials from PL and neighbouring countries):

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	56.8%	65.0%	73.1%	89.6%	87.9%
2 nd assessment	52.0%	63.8%	72.9%	88.8%	87.9%
long term effect	51.9%	58.8%	66.9%	85.0%	83.1%

POLPE – 4 trials: SK (1), RO (3). It is a major weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance POLPE in label. For Poland registration of POLPE on the basis on trials performed in S-E EPPO zone is not possible, this weed should be deleted from Polish label project.

Efficacy for S-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	72.3%	79.8%	85.1%	91.7%	92.6%
2 nd assessment	74.2%	80.7%	86.0%	92.1%	92.5%
long term effect	71.0%	79.8%	84.8%	90.4%	91.7%

SOLNI – 3 trials: PL (2), HU (1). It is a major weed in maize for Poland. It is a major weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance SOLNI in label. For Poland registration of SOLNI is not possible (at least 4 valid trials are required)..

Efficacy for N-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	72.5%	87.5%	97.5%	99.1%	100
2 nd assessment	72.5%	87.5%	100%	100%	100%
long term effect	not studied	92.5%	100%	100%	100%

Efficacy for S-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	100%	100%	100%	100%	100%
2 nd assessment	100%	100%	100%	100%	100%
long term effect	100%	100%	100%	100%	100%

STEME – 2 trials: PL (2). It is a minor weed in maize for Poland. Number of trials for all zones in not sufficient, so each cMS should decide about possibility of acceptance STEME in label. For Poland registration of STEME is possible.

Efficacy for N-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	73.8%	86.3%	90.6%	93.1%	93.8%
2 nd assessment	75.6%	92.5%	93.5%	95.6%	95.6%
long term effect	not studied	not studied	not studied	not studied	not studied

VIOAR – 7 trials: PL (6), DE (1). It is a minor weed in maize for Poland. Applicant submitted sufficient number of trials only for N-E EPPO zone. cMS from Maritime should consider extrapolating results from PL. In the opinion of ZRMs registration of VIOAR in S-E is not possible without any trial. However, final decision is left to each cMS. VIOAR can be included in Polish label.

Efficacy for N-E EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	60.3%	68.5%	78.5%	85.0%	87.2%
2 nd assessment	70.3%	79.2%	91.4%	93.9%	95.0%
long term effect	70.0%	85.6%	95.0%	93.5%	95.0%

Efficacy for Maritime EPPO zone:

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	100%	100%	100%	100%	100%
2 nd assessment	95.0%	100%	100%	100%	100%
long term effect	95.2%	92.8%	97.4%	96.7%	97.6%

Efficacy for Poland (trials from PL and neighbouring countries):

Dose	0.6 L/ha	0.75-0.8 L/ha	1.0 L/ha	1.5 L/ha	St. ref.
1 st assessment	68.3%	73.0%	81.6%	87.1%	89.0%
2 nd assessment	75.3%	82.1%	92.6%	94.8%	95.8%
long term effect	82.5%	89.2%	96.2%	95.1%	96.3%

Applicant correctly presented results. Due to the limited number of results for some particular weeds species, it can be difficult to make a clear conclusion for the label, especially for weeds which are considered to be major. Therefore, the sufficiency of results should be considered on the national level based on importance of weed in their country.

Extrapolations results from registered products containing mesotrione should be considered by individual

member states on a national level based on current registration, data protection and experience with similar active compounds products. The spectrum of weeds should be checked with label claims on these reference products.

ACCEPTED WEED IN POLISH LABEL: When the minimum number of tests was met for the north-east zone, then the weeds were classified only by them (trials from neighboring countries were not considered in this case). On the other hand, when the number of studies for the northeast zone was not sufficient, then PL and neighboring countries' studies were taken into account for classification. POLAV was classified based only on studies from PL, as it appeared to be resistant (eff=0%) in a study from Germany. So, weed classification made by ZRMs and Applicant could be different.

Max. accepted dose was changed due to assessment made by Ecotox section. Ecotox accepted max. 100 g.a.s./ha of mesotrione, so only max dose 1.0 L/ha can be accepted by section efficacy as it was studied during field trials.

Dose 1.5 L/ha:

- ~~• susceptible: weeds: CHEAL, ECHCG, GALAP, GASPA, LAMPU, MATCH, MATIN, POLAV, POLCO, STEME, VIOAR.~~

Dose 1.0 L/ha:

- *susceptible:* weeds: CHEAL, GALAP, GASPA, LAMPU, POLAV, STEME, VIOAR
- *moderately susceptible weeds:* ECHCG, MATIN
- *moderately tolerant weeds:* POLCO
- *tolerant weeds:* MATCH.

Dose 0.75 L/ha:

- *susceptible weeds:* CHEAL, GALAP, LAMPU, STEME, VIOAR
- *moderately susceptible weeds:* ECHCG, GASPA, MATIN, POLAV
- *tolerant weeds:* MATCH, POLCO.

Following weed species were excluded from Polish label due to not sufficient number of trials: AR-BUTH; AGREE; AMABL; ANGAR; AVEFA; BRNN; CIRAR; CHEPO; DATST; PANMI; POLAM; POLLA; SETVI; XANST; AMBEL, HIBTR, AMARE, POLPE and SOLNI.

The dose used should be adjusted according to the species of weeds to be controlled. The lower dose can be used for weeds occurring in low intensity, in the early stages of development.

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

Juzan Extra 100 SC (product code: M-100SC-OR2-C) contains mesotrione (100g/L), a potent bleaching herbicide that belongs to the triketone herbicide family (HRAC Group F2).

Juzan Extra 100 SC is a post-emergence herbicide for the control of weeds in maize with one active substance – mesotrione. Mesotrione belongs to HRAC group F2 (S27) and acts by bleaching, via inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase (4-HPPD). It is a member of the triketone chemical family, in which the active substance sulcotrione is the only other member. Mesotrione disrupts the development of plant pigments which are essential for photosynthesis. This inhibition causes leaf chlorosis and eventual death of sensitive weed species.

Thus, the analysis of the risk for the development of weed resistance to mesotrione is made under the assumption that cross resistance exists between all herbicides classified as HRAC group F2. No cross-resistance was observed between F2 herbicides in the ten cases reported from the US.

The mesotrione resistant Amaranth species (*Amaranthus tuberculatus* and *Amaranthus palmeri*) populations in Iowa, Illinois, Kansas and Nebraska (USA) mentioned in section 3.3.4 were reported to be cross-resistant to ALS inhibitors (HRAC group B/2), Photosystem II inhibitors (HRAC group C1/5), PPO inhibitors (HRAC group E/14), Synthetic Auxins (HRAC group O/4) and/or EPSP synthase inhibitors (HRAC group G/9).

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

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

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

Always follow HRAG guidelines for the prevention and managing herbicide resistant grass and broad-leaved weeds.

Group F2 is one of the modes of action with the fewest cases of resistance reported. At the time of this evaluation (December 2022), there are only two weeds worldwide (*Amaranthus tuberculatus* and *Amaranthus palmeri* in the USA) that have developed resistance to HPPD inhibitors (www.weedscience.org). A total of 8 individual cases of resistance to mesotrione have been observed.

#	Year	Species	Country	MOAs	Actives	Situations
1	2021	<i>Amaranthus tuberculatus</i> (=A. rudis)	Canada (Ontario)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	imazethapyr, atrazine, metribuzin, lactofen, glyphosate, mesotrione	Corn (maize), Soybean, Dry, bean, edible
2	2016	<i>Amaranthus tuberculatus</i> (=A. rudis)	United States (Illinois)	Auxin Mimics HRAC Group 4 (Legacy O), Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), Inhibition of Protoporphyrinogen Oxidase HRAC Group 14 (Legacy E), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	imazethapyr, chlorimuron-ethyl, atrazine, fomesafen, lactofen, acifluorfen, dicamba, 2,4-D, mesotrione, tembotrione, topramezone	Corn (maize), Soybean
3	2011	<i>Amaranthus tuberculatus</i> (=A. rudis)	United States (Iowa)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Enolpyruvyl Shikimate Phosphate Synthase HRAC Group 9 (Legacy G), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	imazamethabenz-methyl, thifensulfuron-methyl, chlorimuron-ethyl, atrazine, isoxaflutole, glyphosate, mesotrione	Corn (maize), Soybean
4	2009	<i>Amaranthus palmeri</i>	United States (Kansas)	Inhibition of Acetolactate Synthase HRAC Group 2 (Legacy B), Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	thifensulfuron-methyl, atrazine, mesotrione, pyrasulfotole, tembotrione, topramezone	Corn (maize), Sorghum
5	2011	<i>Amaranthus tuberculatus</i> (=A. rudis)	United States (Nebraska)	Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2)	mesotrione, tembotrione, topramezone	Corn (maize)
6	2011	<i>Amaranthus palmeri</i>	United States (Nebraska)	Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2)	mesotrione, tembotrione, topramezone	Corn (maize)
7	2014	<i>Amaranthus palmeri</i>	United States (Nebraska)	Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2), PSII inhibitors - Serine 264 Binders HRAC Group 5 (Legacy C1 C2)	atrazine, mesotrione, tembotrione, topramezone	Corn (maize)
8	2016	<i>Amaranthus palmeri</i>	United States (North Carolina)	Inhibition of Hydroxyphenyl Pyruvate Dioxygenase HRAC Group 27 (Legacy F2)	mesotrione	Corn (maize)

Mesotrione has been authorised as a herbicide in Europe for over a decade now, and despite its widespread use in maize, no resistance to this active substance has yet been reported in Europe. There is currently no resistance to any Group F2 herbicides in Europe. Additionally, no cross resistance to mesotrione is known, although this does not mean it cannot develop.

Resistance to mesotrione has not been reported in any of the target weeds of 'Juzan Extra 100 SC'. However, it has been reported in two species within the *Amaranthus* genus, and the target weed AMARE is a member of this genus.

The zRMS would consider that inherent risk of resistance developing to mesotrione to be low. Some of the target weeds e.g. AMARE, ECHCG and CHEAL have an inherently high risk of developing resistance. Therefore, the zRMS would consider the inherent risk of resistance developing towards the target organisms to be moderate to high.

Overall, the zRMS considers that the risk of resistance developing to mesotrione from the proposed use of 'Juzan Extra 100 SC' is low to moderate. The risk comes predominantly from the inherent risk of some of the target weeds. As a result of this risk, an unrestricted use pattern is not acceptable, and modifiers are required. The zRMS considers that the resistance management strategy proposed by the applicant will reduce the risk to an acceptable level.

This represents a low rate of resistance development: In terms of the use pattern, 'Juzan Extra 100 SC' can only be applied once per crop and season, which will also minimise the risk of resistance developing.

The resistance label wording on the proposed Polish label should be as follows: *Juzan Extra 100 SC contains mesotrione which is from a group of herbicides referred to as 4-HPPD inhibitors. This class of compounds act by disrupting the synthesis of certain plant pigments involved in photosynthesis.*

At the present time there is no known cross-resistance to mesotrione in weeds that exhibit resistance or reduced sensitivity to other herbicides with different modes of action. The use of Juzan Extra 100 SC in mixtures and sequences with other herbicides approved for use in grain and forage maize crops and with a different mode of action is recommended to help to reduce the development of resistance. As herbicides in the group of 4-HPPD inhibitors are currently only available in maize crops, crop rotation with the use of herbicides with a different mode of action will also help to reduce the development of resistance. In the event that strains of weeds develop resistance or become less sensitive to a specific herbicide such as mesotrione, weed control may be reduced.

Where maize crops are grown in successive seasons, avoid the use of Juzan Extra 100 SC for more than two successive seasons to avoid the potential for weed resistance developing to mesotrione.

Conclusion The zRMS considers the resistance management strategy to be acceptable and recommends that CMS consider including the relevant advice on their national labels.

3.3.2 Adverse effects on treated crops

In the evaluation process the fact that the active ingredient – mesotrione is used in many plant protection products and have been commonly used in crop protection for many years were taken into consideration by ZRMs. The Applicant submitted in total 19 selectivity studies conducted in different sea-sons (2016-2019) on herbicide (Juzan Extra 100 SC) containing mesotrione as an active substance.

The selectivity evaluation of the herbicide is to be performed according to listed below EPPO guidelines. The evaluation of herbicide selectivity was carried out 4-5 per season. Results were described in percent of destruction of plant for herbicides treatment compared to plant for untreated, where 0% means no phytotoxicity and 100% - complete destruction. Phytotoxicity as-sessment was carried out with the use of different cultivars (commercially grown varieties). Dosages N (recommended by Applicant: 1,5 L/ha) and 2N (doubled recommended: 3.0 L/ha) were studied in all trials. Experimental details and as-sessments methods were in accordance with EPPO standards. Detailed infor-mation's are presented by Applicant in the tables above.

Max. accepted dose was changed due to assessment made by Ecotox section. Ecotox accepted max. 100 g.a.s./ha of mesotrione, so only max dose 1.0 L/ha can be accepted by section efficacy as it was studied during field trials. All field tests have tested a higher dose (1.5 L/ha) than is currently recommended (1.0 L/ha), then all proposed records are valid for the lower dose in the opinion of ZRMs.

Maritime EPPO zone: 8 trials (CZ-3, DE-5). In 4 out of 8 selectivity trials the broadcast spray application of JUZAN EXTRA 100 SC, at 1N and 2N dose of JUZAN EXTRA 100 SC product, no phytotoxicity symptoms were observed at any of the of the assessment timings. Reference products also provided no phytotoxic symptoms at all tested rates. No phytotoxic symptoms were also observed at any of the 7 efficacy trials. Phytotoxic effects observed on the trials were of temporary and vanishing kind and comparable to the reference products. No impact on the crop vigour was observed where in all 8 selectivity and 7 efficacy trials full vigour (100%) was recorded. Additionally, no impact on crop yield was observed.

N-E EPPO zone: 4 trials (PL). Phytotoxicity was assessed in 4 selectivity trials on different cultivars of maize located in North-Eastern EPPO zone. Broadcast spray application of JUZAN EXTRA 100 SC did not induce any phytotoxicity symptom at any of the tested doses (1N and 1,5N), as well as the reference products. Furthermore, no phytotoxicity symptoms were observed in North-Eastern EPPO zone in 6 efficacy trials for application of JU-ZAN EXTRA 100 SC and the reference product Callisto 100 SC or Juzan 100 SC, whatever rate is considered. Additionally, no reduction in crop vigour occurred neither in selectivity nor in efficacy trials.

S-E EPPO zone: 7 trials (SK-1, HU-2, RO-4). Phytotoxic symptoms were not observed in all selectivity and efficacy trials treated with 1N dose of product JUZAN EXTRA 100 SC (150 g a.s./ha of mesotrione) at any assessment timing. For 2N dose of product JUZAN EXTRA 100 SC (300 g a.s./ha of mesotrione) phytotoxic effect was noticed in 5 out of 7 selectivity trials, however phytotoxic effects observed on the trials were of temporary and vanishing kind and comparable to the reference products. No impact on the crop vigour was observed where in 6 selectivity trials. In 1 of the trials slight reduction of crop vigour (-1.5%) was reported for 2N dose rate of product JUZAN EXTRA 100 SC and the reference product. These reductions were not long lasting and vanished after second assessment timing. In 7 efficacy trials full vigour (100%) was recorded. In 1 trial vigour reductions were reported as caused by immense concurrence with the weeds and therefore it should not be assessed as a treatment related symptom. Additionally, no impact on crop yield was observed.

In the opinion of ZRMs, the warning should be put on the label: e.g. Phytotoxicity cannot be excluded. Sensitivity of varieties should be consulted with the authorization holder.

3.3.3 Observations on other undesirable or unintended side-effects

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

Mesotrione is taken up by both plant roots and shoots and has residual activity in the soil (Cornes, 2001). Residual herbicides provide the benefit of prolonged weed control in the crop, but under certain environmental conditions may persist longer than expected and this is dependent on the herbicide used (Colquhoun, 2006). The half-life of mesotrione in soil ranges from 5 to as much as 62 days (Dyson, 2002), depending on soil type, organic carbon and soil pH. Literature data indicate that HPPD (mesotrione) herbicide carryover can occur, especially in fields whose soil texture is sandy or sandy loam; or after fertilizer application after anhydrous ammonia has been "knocked in." Long strips of bleached plants could be seen throughout the field, where anhydrous ammonia caused a local change in soil pH, thus causing the release of mesotrione residues from soil colloids. Therefore, the impact on succeeding crops should be noted. Mesotrione is a prevalent herbicide used to control weeds in maize crops, but it is susceptible to degradation and leaching in soil.

Applicant presented information in accordance with the EPPO guideline PP 1/207 (2) "Effects on succeeding crops". The study on the toxicity to non-target terrestrial plants has been carried out with Juzan

Extra 100 SC (M-100SC-OR2-C). Details are presented in section 9 (chapter 9.10). The highest value ER10 was noted for oat (210.39), soybean (104.35) and onion (91.26).

Available sources in literature treating on herbicide mesotrione says that in the case of sensitive crops, ie. sugar, legumes, oilseed rape, sunflower and vegetables and early sown winter cereals in unfavorable conditions for decomposition of the possible occurrence of damage. So, ZRMs accepted entry proposed by Applicant in the label: *If it is necessary to plow a plantation treated with the product in advance (as a result of damage to corn by hail, disease, pests or frost), only corn grown for grain or intended for fodder can be grown on the field. At the same time, it should be borne in mind that immediately after emergence, temporary and quickly transient phytotoxic symptoms may appear. After harvesting corn grown under normal growing conditions, weeded with JUZAN EXTRA 100 SC after plowing to a depth of min. 20 cm, winter cereals can be sown. On the other hand, all crops can be cultivated in the spring. In the case of cultivation of sensitive crops, i.e. beet, faba bean, winter oilseed rape, sunflower and vegetables, as well as early sown winter cereals in conditions unfavorable for the decomposition of the agent (easily drying soils with pH<6.0, soils with high organic matter content >4.0%, low biological activity, exceptionally low temperatures in winter, exceptionally low soil moisture in summer and/or autumn and/or winter, overlapping of the surface sprayed with the agent) damage to the crop is possible.*

Generally, the product is a foliar herbicide effective on broadleaved weeds. Therefore, warnings to avoid spray drift on adjacent crops should appear on the label.

Summarizing results achieved above. an acceptable risk is indicated for Cabbage. Soybean. Onion. Oat even when no buffer strip is applied. For Tomato and Lettuce 3 m buffer strip is needed. The respective TER values are >1 as requested in EPPO guideline PP 1/256. No further testing required.

During the performance of trials referred to in this dossier, no observations were recorded on negative or positive effects of Juzan Extra 100 SC on beneficial or other non-target organisms.

3.4 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the active substance and three relevant impurities in the plant protection product.

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

The methods were successfully evaluated and meet the EU criteria with respect to specificity, linearity, accuracy and precision according to the guidance document SANCO/3030/99.

3.4.1 Analytical method for the formulation

An overview on the acceptable methods for analysis of mesotrione in plant protection product is provided as follows:

	Mesotrione
Author(s), year	Wołoszynowska M., 2020
Principle of method	Method validation for determination of the Mesotrione content was performed using high performance liquid chromatography (HPLC) with DAD detector and external standard method.

	Mesotrione
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	The linearity of the detector response was assessed using five standard solutions at the concentration range of Mesotrione 60.93 mg/l to 142.17 mg/l (61% - 142% mesotrione content). Linear equation: $y = 18174x - 35763$ Correlation coefficient: 0.9996 (acceptance criterion $R^2 \geq 0.99$) The obtained results are acceptable.
Precision – Repeatability Mean n = 6 (%RSD)	RSD = 1.11% acceptance criterion: < 1.90% Hr = 0.58 acceptance criterion: ≤ 1
Accuracy n = 12 (% Recovery)	Mean total recovery: 100.15% acceptance criterion: 100% \pm 3%
Interference/ Specificity	No interference
Comment	Suitable for verification of analyte in the nominal concentration range

Mesotrione contains three relevant impurities: 1,2-dichloroethane, 1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one (IMP 1) (R287431) and 6-(methylsulfonyl)-9-oxo-9H-xanthene-1-carbonitrile (IMP 2) (R287432). Presented methods validation for determination of that three relevant impurities content in the formulation are adequate and fully meet the requirements according SANCO/3030/99 rev. 5.
 An overview on the acceptable methods for analysis of relevant impurities in plant protection product is provided as follows:

	1,2-dichloroethane max. 1 mg/kg	IMP 1 (R287431) max. 2 mg/kg	IMP 2 (R287432) max. 2 g/kg
Author(s), year	Wołoszynowska M., 2020		
Principle of method	Method validation for determination of the 1,2-dichloroethane content was performed by headspace analysis in combination with gas chromatography and flame ionization detection (HS-GC-FID) using external standard method. Confirmation: GC-MS technique with electron impact ionization (EI).	Method validation for determination of IMP 1 (R287431) and IMP 2 (R287432) content was performed using ultra high performance liquid chromatography (UHPLC) with MS/MS detection and external standard method.	
Linearity (linear between mg/L) (correlation coefficient, expressed as r)	The linearity of the detector response was assessed using six solutions in the range of 1,2-dichloroethane content from 0.0005 mg to 0.010 mg (corresponding to 5% - 105% w/w of maximum content of 1,2-dichloroethane in 100 mg of preparation).	The linearity of the detector response was assessed using six solutions at the concentration range of IMP 1 from 0.4959 ng/ml to 9.0922 ng/ml (corresponding to 7.08% - 129.89% of maximum content of IMP 1 in	The linearity of the detector response was assessed using six solutions at the concentration range of IMP 1 from 0.9368 ng/ml to 32786.5 ng/ml (corresponding to 0.01% - 468.38% of maximum

	1,2-dichloroethane max. 1 mg/kg	IMP 1 (R287431) max. 2 mg/kg	IMP 2 (R287432) max. 2 g/kg
	Linear equation: $y = 880\,621.8x - 33.55$ Correlation coefficient: 0.9994 (acceptance criterion $R^2 \geq 0.99$) The obtained results are acceptable.	preparation). Linear equation: $y = 2\,909.9x - 60.096$ Correlation coefficient: 0.9969 (acceptance criterion $R^2 \geq 0.99$) The obtained results are acceptable.	content of IMP 2 in preparation). Linear equation: $y = 2\,292.6x + 629\,853$ Correlation coefficient: 0.9985 (acceptance criterion $R^2 \geq 0.99$) The obtained results are acceptable.
Precision – Repeatability Mean (%RSD)	n = 6 RSD = 2.52% acceptance criterion: < 7.37% Hr = 0.34 acceptance criterion: ≤ 1	n = 5 RSD = 4.85% acceptance criterion: < 17.83% Hr = 0.27 acceptance criterion: ≤ 1	n = 5 RSD = 5.49 % acceptance criterion: < 8.11 % Hr = 0.68 acceptance criterion: ≤ 1
Recovery	Assessed at two levels of concentration (n=12). Mean total recovery [%]=100.6 RSD[%]=1.68	Assessed at two levels of concentration (n=12). Mean marginal recovery [%]=109.8 RSD[%]=3.56	Assessed at two levels of concentration (n=12). Mean marginal recovery [%]=109.53 RSD[%]=3.30
Accuracy n = 12 (% Recovery)	100.6% acceptance criterion: 100 ± 30	109.8% acceptance criterion: 100 ± 30	109.53% acceptance criterion: 100 ± 30
Interference/ Specificity	To prove specificity the following chromatograms were performed and superimposed: mixture DMSO and deionized water, placebo of M-100SC-OR2-C, specimen of M-100SC-OR2-C. No interference	The chromatograms of solvent, standard solution, placebo solution and the examined specimen solution were performed and superimposed. No interference	
LOQ	Limit of quantification is 0.0005 mg what corresponds to 0.0005% of maximum 1,2-dichloroethane content in M-100SC-OR2-C preparation.	Limit of quantification is 0.4959 ng/ml what corresponds to 0.000014 g/kg of IMP 1 in M-100SC-OR2-C preparation i.e. 0.000139 g/kg in Mesotrione	Limit of quantification is 0.93676 ng/ml what corresponds to 0.000026 g/kg of IMP 2 in M-100SC-OR2-C preparation i.e. 0.000262 g/kg in of Mesotrione
Comment	-	-	-

3.4.2 Analytical methods for residues

Adequate analytical methods are available to monitor all compounds given in the respective residue definition of mesotrione in food of plant and animal origin, soil, water and air. All this analytical methods are active substance data and were provided in the EU review of Mesotrione or access to them is covered by alternative data package. Data Matching List covers all the protected studies from the main notifier. An

Applicant – Ciech Sarzyna S.A. posses LoA to that Data.

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

Noticed data gaps are:

- none

Commodity/crop	Supported/ Not supported
Maize (ZEAMX)	Supported
Sugar maize (ZEAMS)	Supported
Popcorn (ZEAME)	Supported

3.5 Mammalian toxicology (Part B, Section 6)

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. For further details please refer to point 3.5.2-3.5.4 presented below.

3.5.1 Acute toxicity

The product Juzan Extra 100 SC containing mesotrione has a low toxicity in respect to acute oral, inhalation and dermal toxicity. It is also not irritant for skin and eyes and not sensitising to skin.

However due to presence and harmonised classification of mesotrione, Juzan Extra 100 SC should be labelled as suspected of damaging the unborn child with the H361d statement and H373 – May cause damage to organs through prolonged or repeated exposure (eye and nerves system) and contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. [EUH 208]

3.5.2 Operator exposure

According to EFSA GD Exposure Calculator at the 75th percentile, operator exposures were estimated for maximum application rates of mesotrione to maize and against the AOEL agreed in the EU review for this active substance. Results show that the risk for the operator using Juzan Extra 100 SC with the vehicle mounted sprayer is acceptable when the operator using work wear (arms, body and legs covered) Mixing/Loading and Application + gloves.

3.5.3 Worker exposure

The results of the exposure estimations based on EUROPOEM II calculator show that the use of Juzan Extra 100 SC according intended uses presented in GAP Table, causes no health risk for the worker when using wearing work wear (arms, body and legs covered) and gloves

3.5.4 Bystander and resident exposure

The estimations performed according to EFSA calculator indicate that the systemic exposure of resident to mesotrione contained in the formulation Juzan Extra 100 SC does not exceed the values of AOEL for this active substance.

The incidental short-time exposure of bystander and resident (children and adult) to mesotrione contained in the formulation Juzan Extra 100 SC causes no risk to human health if the product is used in accordance to the intended uses listed in the GAP Table and when the following risk mitigation measures are applied:

- **Drift reduction**
- **5 m buffer strip**
- **Information table: “No entry for residents to area treated with plant protection product”.**

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

3.6.1 Residues

Storage stability

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

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

Metabolism in plants and animals

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

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

Plant residue definition for risk assessment:

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

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

Magnitude of residues in plants

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

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

According to SANTE/2019/12752, extrapolation from immature maize to sweet corn is possible. The residue trials conducted in maize could also be used to support the intended GAP use of sweet corn (taken before BBCH 85).

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

Magnitude of residues in livestock

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

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

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

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

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

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

Magnitude of residues in processed commodities

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

Magnitude of residues in representative succeeding crops

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

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

Other / special studies

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

Estimation of exposure through diet and other means

The proposed uses of mesotrione in the formulation Juzan Extra 100 SC do not represent unacceptable acute and chronic risks for the consumer. Calculations are accepted.

3.6.2 Consumer exposure

A consumer risk assessment was performed using the EFSA PRIMo model rev. 3.1. TMDI calculations were performed taking into account all commodities for which MRLs have been set for the active substance mesotrione, using as input values the EU-MRLs in force. The chronic exposure was up to 12% of the ADI for mesotrione. IESTI calculations for the intended crops were well below (up to 2%) the respective ARfD.

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

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

The PEC values of Juzan Extra 100 SC, mesotrione and its metabolites in soil have been assessed with the ESCAPE model (Version 2.0, 5 September 2017), the focus groundwater interception values taken from FOCUS guidance (Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version: 2.2, May 2014)) and the DT₅₀ values established in the EU peer review for mesotrione (EFSA Journal 2016;14(3):4419).

The PEC_{soil} values for the active substance were used in the eco-toxicological risk assessment for the intended uses of the plant protection product Juzan Extra 100 SC.

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

Results of modelling with FOCUS PELMO & PEARL show that the active substance mesotrione and metabolite AMBA are not expected to penetrate into groundwater at concentrations of $\geq 0.1\mu\text{g/L}$ in the intended uses of Juzan Extra 100 SC in maize & sugar maize.

For metabolite MNBA unacceptable leaching was observed for maize & sugar maize crops in scenario Hamburg using PEARL (0.106 µg/L) and PELMO (0.131 µg/L) models. The exceedance of the threshold concentration was also observed in acidic soils. No unacceptable leaching was observed in neutral and alkaline soils.

Additionally, PEC_{GW} calculations were performed with the FOCUS MACRO. The results of the simulations in MACRO indicate that PEC_{GW} of active substance mesotrione and its metabolite (excluding AMBA) stayed below 0.1 µg/L in Châteaudun scenario.

The information concerning the environmental metabolite MNBA and assessment of his potential relevance with respect to the current SANCO guidance (SANCO/221/2000 rev.10, 25/02/2003) is provided in the dRR of Juzan Extra 100 SC, Section 10 (Assessment of the relevance of metabolites in groundwater).

Taking above information into account, it could be stated that the use of Juzan Extra 100 SC according to recommendations will not pose a risk of groundwater contamination by mesotrione and its metabolites (AMBA and MNBA).

All details on the calculations are included in the Report RR/02/22 attached to Part B, Section 8.

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

In accordance with the applicable requirements calculation of the PEC_{sw} and PEC_{sed} values for the active substance and relevant metabolites in surface waters were presented. The calculations were carried out taking into consideration of data for active substance and metabolites listed in the „EFSA Journal 2016;14(3):4419, Conclusion on the peer review of the pesticide risk assessment of the active substance mesotrione”.

The initial, short-term and long-term (actual and average time-weighted) values of PEC_{sw} and PEC_{sed} were calculated for acetamiprid and appropriate metabolites using STEPS 1-2 in FOCUS v.3.2, FOCUS SWASH v.5.3, FOCUS PRZM v.4.3.1, FOCUS MACRO v.5.5.4, FOCUS TOXSWA v.5.5.3 and SWAN v.5.0.1. Moreover, the PEC_{sw} and PEC_{sed} were calculated for metabolites such as AMBA, MNBA and following the FOCUS SW scheme up to Step 2. As the PEC_{sw} values of mesotrione derived from Step 3 indicated a possible risk for aquatic organisms, a calculation of PEC_{sw} values based on higher tier modelling (Step 4) was necessary. Calculations of PEC_{sw} using Step 4 were performed taking into account different mitigation measures. Higher tier Step 3 and Step 4 of further metabolites were not required for the aquatic risk assessment.

All details on the calculations are included in the Report RR/06/22 attached to Part B, Section 8.

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

Taking into account mesotrione vapour pressure <10⁻⁵ Pa, no unacceptable volatilisation from plant and soil surfaces is anticipated. Air DT50 <2 days indicates that mesotrione is not persistent in the air and for this reason will not be a subject of the short- or long-term transport. On the basis of available data no unacceptable contamination of the atmosphere is expected following application of Juzan Extra 100 SC according to the recommended use pattern.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

The acute and long-term risks of Juzan Extra 100 SC to birds were assessed from toxicity exposure ratios

between toxicity endpoints estimated from studies with mesotrione and maximum residues occurring on food items following applications according to the proposed use pattern. The risk to birds from exposure via drinking water was also assessed and showed acceptable risk. Risk of secondary poisoning for mesotrione was not assessed as the log Pow is <3.0.

In the screening step the TER_A values for mesotrione exceeds the trigger value (10), indicating that Juzan Extra 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 Juzan Extra 100 EC 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 was not accepted by zRMS.

In the Core Dossier, no safe use was concluded following application of Juzan Extra 100 EC at 1.5 L/ha (corresponding to 150 g a.s./ha) and further refinement is required.

The National Addendum for Poland containing supplementary information with refinement risk assessment for mammals for Juzan Extra 100 EC was submitted by the Applicant.

In the Core Dossier, due to unacceptable reproductive risk to mammals in post-emergence use as the risk refinement new residue decline study to determine DT_{50} of mesotrione in maize (Peda T., 2021, SGS study code: 21SGS76) were presented. In the Core refinement of DT_{50} was not accepted by RMS, due to the uncertainties related to the kinetic analysis of the data of the residue trials. In order to respond to the evaluators' requirements, the refined kinetic evaluation was performed by Applicant. The kinetic analysis was accepted by RMS. The $DT_{50} = 1.36d$ as geometric 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 $DT_{50} = 1.44d$ and this value should be used in risk assessment. Estimated new f_{TWA} based on residue decline study will be used as a risk refinement for reproductive risk to mammals in post-emergence use.

The presented by the Applicant refinement risk assessment for the vertebrates was evaluated by the RMS. The DT_{50} value of 1.44 days was considered adequate and taken into account in the risk assessment for mammals. Based on the new f_{TWA} , application for rabbit is still unacceptable. The RMS proposes to reduce the dose to 0.100 kg s.a./ha. New calculation was provided by RMS based on reduced dose (0.100 kg s.a./ha). The trigger value for rabbit and *Apodemus sylvaticus* are above the trigger of 5. Therefore, further refinement is not required for this species as the TER_{LT} is above the trigger of 5 indicating acceptable risk to mammals.

3.8.2 Effects on aquatic species

Based on PEC/RAC calculations, no unacceptable risk is indicated for aquatic organisms considering all envisaged GAP uses for Juzan Extra 100 SC, assuming that following risk mitigation measures are taken into account:

- a vegetative buffer strip of 20m to surface water bodies is required when conventional spraying techniques are applied.

3.8.3 Effects on bees

The evaluation of the risk for bees has been performed in line with SANCO/10329/2002 rev 2 final.

Based on results obtained in oral and contact studies on honeybees all calculated hazard quotients are considerably less than trigger values, indicating that the formulation poses a low risk to bees. Therefore, a low risk to bees is expected from the application Juzan Extra 100 SC according to the proposed GAP and no mitigation measures are required.

According to Commission regulation (EU) No 284/2013, point 10.3.1. (Effects on bees): the Applicant provided also the chronic test on bees and chronic test for larvae for formulated product.

3.8.4 Effects on other arthropod species other than bees

The risk assessment was conducted according to the ESCORT 2 Guidance Document (2000) and the Guidance Document on Terrestrial Ecotoxicology (2002).

The in-field and off-field risk from exposure to mesotrione applied as Juzan Extra 100 SC for the intended uses in major and minor crops is indicated to be acceptable for non-target arthropods other than bees based on Tier 2 data without the need for risk mitigation measures.

3.8.5 Effects on soil organisms

The risk from exposure to mesotrione and relevant soil degradation products applied as Juzan Extra 100 SC for all intended uses is indicated to be acceptable for the soil meso- and macrofauna.

The risk to soil microorganisms is acceptable since negligible effects on the nitrogen transformations are foreseen at higher levels than the calculated PEC soil values for the active when the intended use of pattern for the Juzan Extra 100 SC is considered.

3.8.6 Effects on non-target terrestrial plants

For the proposed use of Juzan Extra 100 SC, based on the highest application rate the risk for non-target plants in the off-crop area is indicated to be acceptable when either :

- 1 m buffer strip with 90% drift reduction or,
- 5 m buffer strip with 50% drift reduction or,
- 10 m buffer strip with no drift reduction

is applied as the risk mitigation measure.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further relevant data available and considered necessary.

3.9 Relevance of metabolites (Part B, Section 10)

Following metabolite of mesotrione has the potential to reach the groundwater in concentrations above 0.1 µg/L: MNBA.

All details are included in Part B, Section 10 of this dRR.

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

Not required because mesotrione is not classified as candidate for substitution.

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

Appendix 1 Copy of the product authorization



Appendix 2 Copy of the product label

UWAGI DO ETYKIETY:

Fizyko-chemia: ~~Badania 2-letnie w toku.~~ Brak uwag.

Skuteczność: w prowadzono zmiany do listy zaakceptowanych chwastów oraz zmodyfikowano skalę ich wrażliwości. Pozostałe zapisy w etykiecie zaakceptowano. Wykreślono z etykiety chwasty dla dawki 1.5 L/ha z uwagi na jej brak akceptacji przez inną sekcję.

Toksykologia: dodano zwroty H373 i P314.

Metabolizm i pozostałości: brak uwag.

Los i zachowanie w środowisku: brak uwag

Ekotoksykologia: ~~Brak zaakceptowanego zastosowania. Dalsze kalkulacje dotyczące uściślenia oceny ryzyka długoterminowego dla ssaków powinny być przedstawione przez Wnioskodawcę. Dalsze kalkulacje dotyczące uściślenia oceny ryzyka dla ssaków w związku z zanieczyszczonej wodą pitną w kałużach również powinny zostać dostarczone przez Wnioskodawcę.~~

Ze względu na uściślenie oceny ryzyka dla ssaków konieczne jest zmniejszenie dawki do 0.100 kg s.a./ha.

W celu ochrony organizmów wodnych konieczne jest zastosowanie 20 metrowej zadarniowej strefy ochronnej od zbiorników i cieków wodnych.

W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości: 10 m od terenów nieużytkowanych rolniczo lub 5 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50% bądź 1 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.

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

Posiadacz zezwolenia:

CIECH Sarzyna S.A., ul. Chemików 1, 37-310 Nowa Sarzyna, tel.: +48 17 24 07 111, e-mail: sarzyna@ciechgroup.com, www.ciechagro.pl


JUZAN EXTRA 100 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

mezotrion (związek z grupy triketonów) – 100 g/l (9,38%)

Zezwolenie MRiRW nr R - z dnia

	
Uwaga	
H361d	Podejrzewa się, że działa szkodliwie na dziecko w łonie matki.
H373	Może powodować uszkodzenie narządów <oczy, system nerwowy> poprzez długotrwałe lub powtarzane narażenie
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
EUH 208	Zawiera 1,2-benzisothiazolin-3(2H)-on. Może powodować wystąpienie reakcji alergicznej.
P280	Stosować rękawice ochronne/odzież ochronną
P308+P313	W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę le
P314	W przypadku złego samopoczucia zasięgnąć porady/zgłosić się pod opiekę lekarza.
P391	Zebrać wyciek.
P405	Przechowywać pod zamknięciem.
P501	Zawartość/pojemnik usuwać zgodnie z przepisami miejscowymi/regionalnymi/narodowymi / międzynarodowymi

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany nalistnie, w postaci koncentratu w formie stężonej zawiesiny do rozcieńczania wodą.

Zgodnie z klasyfikacją HRAC substancja czynna mezotrion zaliczana jest do grupy F2.

DZIAŁANIE NA CHWASTY

Środek jest selektywnym herbicydem o działaniu układowym. Pobierany jest głównie poprzez liście oraz dodatkowo poprzez korzenie chwastów i szybko przemieszczany w roślinie, hamując jej wzrost i rozwój. Powoduje zahamowanie biosyntezy karotenoidów w roślinach chwastów, w następstwie czego następuje zniszczenie chlorofilu, objawiające się bieleniem liści. Pierwsze objawy działania środka widoczne są po 5-7 dniach od wykonania zabiegu. Zamieranie chwastów następuje po około 14 dniach. Środek stosować po wschodach chwastów w fazie 2-8 liści właściwych kukurydzy. Optymalną skuteczność działania uzyskuje się kiedy chwasty znajdują się w fazie 4 liści właściwych (BBCH 14).

Dawka 0,75 l/ha

Chwasty wrażliwe:

gwiazdnica pospolita, jasnota purpurowa, komosa biała, psianka czarna, szarłat szorstki, żółtlica drobnokwiatowa, przytulia czepna, fiołek polny

Chwasty średniowrażliwe: chwastnica jednostronna, fiołek polny, maruna bezwonna, żółtlica drobnokwiatowa, maruna nadmorska, rdest ptasi

Chwasty odporne: rdest powojowaty, rumianek pospolity

Dawka 1,0 l/ha

Chwasty wrażliwe: gwiazdnica pospolita, jasnota purpurowa, komosa biała, psianka czarna, szarłat szorstki, żółtlica drobnokwiatowa, fiołek polny, przytulia czepna, rdest ptasi

Chwasty średniowrażliwe: chwastnica jednostronna, maruna bezwonna, przytulia czepna, rdest powojowaty, rdest ptasi

Chwasty średniodoporne: rdest powojowaty

Chwasty odporne: rumianek pospolity

Dawka 1,5 l/ha

Chwasty wrażliwe: chwastnica jednostronna, fiołek polny, gwiazdnica pospolita, jasnota purpurowa, komosa biała, maruna bezwonna, przytulia czepna, psianka czarna, rdest powojowaty, rdest ptasi, rumianek pospolity, szarłat szorstki, żółtlica drobnokwiatowa, rdest powojowaty

Uwaga:

W celu osiągnięcia wysokiej skuteczności zwalczania chwastnicy jednostronnej zaleca się stosować środek, gdy znajduje się w fazie 2-4 liści właściwych.

STOSOWANIE ŚRODKA

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

Kukurydza

Termin stosowania środka: środek stosować w fazie 2-8 liści kukurydzy (BBCH 12-18)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,5 l/ha 1.0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,75 - 1,5 l/ha-1.0 l/ha

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 – 400 l/ha.

Zalecane opryskiwanie: średniokropliste.

Uwaga:

Stosowaną dawkę należy dostosować do gatunku zwalczanych chwastów. Niższa dawka może być stosowana w przypadku chwastów występujących w niskim nasileniu, we wczesnych fazach rozwojowych.

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOBSZAROWYCH

**Odpowiedzialność za skuteczność działania i fitotoksyczność
środka ochrony roślin stosowanego w uprawach małoobszarowych
ponosi wyłącznie jego użytkownik**

Kukurydza cukrowa, kukurydza pękająca

Termin stosowania środka: środek stosować w fazie 2-8 liści kukurydzy (BBCH 12-18)

Maksymalna/zalecana dawka dla jednorazowego zastosowania: ~~1,5 l/ha~~ 1,0 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,75 - ~~1,5 l/ha~~ 1,0 l/ha

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 – 400 l/ha.

Zalecane opryskiwanie: średniokropliste.

NASTĘPSTWO ROŚLIN

W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem (w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na polu można uprawiać jedynie kukurydzę uprawianą na ziarno lub przeznaczoną na paszę. Jednocześnie należy się liczyć, że zaraz po wschodach mogą pojawić się tymczasowe i szybko przemijające objawy fitotoksyczne. Po zbiorze kukurydzy uprawianej w normalnych warunkach wegetacji, odchwaszczanej środkiem JUZAN EXTRA 100 SC po wykonaniu orki na głębokość min. 20 cm można wysiewać zboża ozime. Natomiast na wiosnę można uprawiać wszystkie uprawy. W przypadku uprawy roślin wrażliwych tj. buraka, roślin bobowatych, rzepaku ozimego, słonecznika i warzyw oraz wcześniej sianych zbóż ozimych w warunkach niekorzystnych dla rozkładu środka (gleby łatwo przesychające o pH<6.0, gleby o wysokiej zawartości substancji organicznej >4.0%, niskiej aktywności biologicznej, wyjątkowo niskich temperaturach w okresie zimowym, wyjątkowo niskiej wilgotności gleby latem i/lub jesienią i/lub zimą, nakładanie się powierzchni opryskanej preparatem) możliwe jest wystąpienie uszkodzeń rośliny uprawnej.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

1. Opryskiwać co najmniej 6 godzin przed spodziewanym deszczem – zawsze z włączonym mieszadłem.
2. Strategia zarządzania odpornością
W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:
 - postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
 - dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
 - stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
 - stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
 - stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),

- dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
 - używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
 - używać kwalifikowanego materiału siewnego, – czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
 - informować posiadacza zezwolenia o nie satysfakcjonującym zwalczaniu chwastów,
 - w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.
3. Środka nie stosować:
- na rośliny osłabione lub uszkodzone przez szkodniki, przymrozki, zalanie lub suszę,
 - podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.
4. Podczas stosowania środka nie dopuścić do:
- znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed zabiegiem wyczyścić dokładnie wszystkie filtry w opryskiwaczu.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. Wypełnić zbiornik do połowy czystą wodą i rozpocząć łagodne mieszanie. Zawartością opakowania przed użyciem wstrząsnąć. Dodać wymaganą ilość produktu do zbiornika i odczekać, aż zostanie w pełni zdyspergowany. Opróżnione opakowania przepłukać trzykrotnie wodą za pomocą zintegrowanej płuczki ciśnieniowej lub ręcznie, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Nie przerywać mieszania aż do zużycia mieszaniny. Oprysk prowadzić natychmiast po wymieszaniu. Nie pozostawiać cieczy użytkowej w urządzeniu do oprysku.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej należy:

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

Po pracy aparaturę dokładnie wymyć.

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

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

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

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

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

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

Zanieczyszczonej odzieży ochronnej nie wnosić poza miejsce pracy.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji): nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

Przestrzegać 5 m strefę buforową oraz umieścić tablice z ostrzeżeniem dla rezydentów i osób przypadkowych, że nie wolno wchodzić na teren na którym zastosowano środek

W czasie oprysku należy zastosować techniki zmniejszające znoszenie preparatu (dysze antyznoszeniowe, mała prędkość pojazdu, stabilna pogoda i inne).

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 20 m od zbiorników i cieków wodnych.

W celu ochrony roślin niebędących celem działania środka konieczne jest:

- wyznaczenie nieopryskiwanej strefy ochronnej od terenów nieużytkowanych rolniczo o szerokości 1m w połączeniu z techniką redukującą znoszenie cieczy użytkowej (90%) lub
- wyznaczenie nieopryskiwanej strefy ochronnej od terenów nieużytkowanych rolniczo o szerokości 5m w połączeniu z techniką redukującą znoszenie cieczy użytkowej (50%) lub
- wyznaczenie nieopryskiwanej strefy ochronnej od terenów nieużytkowanych rolniczo o szerokości 10m.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

– w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,

– w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,

– w temperaturze 0°C - 30°C.

Chronić przed mrozem.

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

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

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

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

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

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

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

The Letters of access were submitted directly to the authority.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.5.1 KCP 2.5.2 KCP 2.6.1 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.8.7.2	Enzo Arévalo	2021	M-100SC-OR2-C Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and low temperature. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Poland Report No.: BF-59/20 GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 2.2.1	Buczkowski D.	2021	M-100SC-OR2-C. Determination of explosive properties Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Poland Report No.: BW-04/21 GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.2 KCP 2.3.1 KCP 2.3.3	Flasińska P.	2021	M-100SC-OR2-C. Determination of flash point, auto-ignition temperature and oxidizing properties Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Poland Report No.: BC-05/21 GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 2.7.5	Kupiec J.	2022	M-100SC-OR2-C Part II: Determination of physicochemical properties after the second year of storage Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Poland Study code no. BF- 59/20 GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 2.4.1_1 KCP 2.8.7.2_1	Kupiec J.	2022	Annex No 1 to Report M-100SC-OR2-C Part I: Determination of physicochemical properties of the initial preparation, after accelerated storage and low temperature. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Poland Report No.: BF-59/20 GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 5.1.1	Bajdor K.	2020	M-100SC-OR2-C, Method validation for determination of the active substance and three relevant impurities content in the formulation Łukasiewicz Research Network – Institute of Industrial Organic Chemistry 1/20/041/K	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 5.1.2/01 (KCP 10.1.2/01)	Peda T. Niewelt S. (analytical phase)	2021	Magnitude of residues of Mesotrione in maize (Raw Agricultural Commodity) after one application of M-100SC-OR2-C – four decline curve studies in Poland, Germany, Hungary and Northern France - 2021 No. 21SGS76 SGS Poland, Warszawa GLP, Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 5.1.2/02	Biesiada M.	2020	Validation of analytical method for the determination of active substance – mesotrione in deionized water SORBOLAB Research Laboratory LLC 0016/0090/FA GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 5.1.2/03	Biesiada M.	2020	Validation of analytical method for the determination of active substance – mesotrione in 50% sucrose solution SORBOLAB Research Laboratory LLC 0016/0092/FA GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 5.1.2/04 (KCP 10.6.2/01)	Dec W.	2021	Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test according to OECD Guideline No. 208 (2006) Study code: EMI/4/10/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2/05 (KCP 10.6.2/02)	Dec W.	2021	Terrestrial Plant Test: Vegetative Vigour Test according to OECD Guideline No. 227 (2006) Study code: EMI/4/9/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 5.1.2/06 (KCP 10.2.1/03)	Szlauer S.	2022	Fresh Alga and Cyanobacteria, Growth Inhibition Test according to OECD Guideline No. 201 (2011) Study code: EMI/4/3/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 5.1.2/07 (KCP 10.2.1/04)	Szlauer S.	2022	Lemna sp., Growth Inhibition Test according to OECD Guideline No. 221 (2006) Study code: EMI/4/6/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 5.1.2/08 (KCP 10.2.1/01)	Szlauer S.	2022	Daphnia sp., Acute Immobilisation Test according to OECD Guideline No. 202 (2004) Study code: EMI/4/5/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 5.1.2/09 (KCP 10.2.1/02)	Szlauer S.	2022	Fresh Alga and Cyanobacteria, Growth Inhibition Test according to OECD Guideline No. 201 (2011) Study code: EMI/4/2/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-1 KCP 6.4-1	Eberhart A.	2017	Determination of Efficacy of Mezotrion 100 SC and Nikosar 060 OD against broadleaved weeds and grasses in corn 2016 Eurofins Agroscience Services Sp. z.o.o S16-02947-01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-2 KCP 6.4-2	Eberhart A.	2017	Determination of Efficacy of Mezotrion 100 SC and Nikosar 060 OD against broadleaved weeds and grasses in corn 2016 Eurofins Agroscience Services Sp. z.o.o S16-02949-01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-3 KCP 6.4-3	Eberhart A.	2017	Determination of Efficacy of Mezotrion 100 SC and Nikosar 060 OD against broadleaved weeds and grasses in corn 2016 AGRITEC, research, breeding and services Ltd. S16-02952-01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-4 KCP 6.4-4	Eberhart A.	2017	Determination of Efficacy of Mezotrion 100 SC and Nikosar 060 OD against broadleaved weeds and grasses in corn 2016 Fyse, Ltd. Dep. Agrolab S16-02953-01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-5 KCP 6.4-5	Eberhart A.	2017	Determination of Efficacy of Mezotrion 100 SC and Nikosar 060 OD against broadleaved weeds and	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			grasses in corn 2016 Eurofins Agroscience Services S.R.L. S16-02954-01 GEP Unpublished				S.A.
KCP 6.2-6 KCP 6.4-6	Matusiak J.	2019	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize, Poland 2019 Fertico Sp. z o.o. 155_01_F19_276 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-7 KCP 6.4-7	Matusiak J.	2019	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize, Poland 2019 Fertico Sp. z o.o. 156_01_F19_277 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-8 KCP 6.4-8	Matusiak J.	2019	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize, Poland 2019 Fertico Sp. z o.o. 157_01_F19_278 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-9 KCP 6.4-9	Matusiak J.	2019	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize, Poland 2019 Fertico Sp. z o.o.	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			158_01_F19_279 GEP Unpublished				
KCP 6.2-10 KCP 6.4-10	Křížek S.	2020	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize, Czech Republic, 2019 SynTech Research Czech Republic s.r.o. SRCZ19-055-428HE GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-11 KCP 6.4-11	Šmahel P.	2020	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize, Czech Republic, 2019 SynTech Research Czech Republic s.r.o. SRCZ19-057-428HE GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-12 KCP 6.4-12	Hetterich A.	2019	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize in Hetterich Fieldwork GbR M-100SC-OR2-C_DE19_EFF01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-13 KCP 6.4-13	Hetterich A.	2019	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize in Hetterich Fieldwork GbR M-100SC-OR2-C_DE19_EFF03 GEP	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 6.2-14 KCP 6.4-14	Barasits T.	2019	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize SynTech Research Hungary Kft. SRHU19-598-428HE GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-15 KCP 6.4-15	Barasits T.	2019	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize SynTech Research Hungary Kft. SRHU19-599-428HE GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-16 KCP 6.4-16	Botoman G.	2019	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize AgroProspect SRL M-100SC-OR2-C_RO19_EFF01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-17 KCP 6.4-17	Botoman G.	2019	Efficacy evaluation of M-100SC-OR2-C in post-emergence application against weeds in maize AgroProspect SRL M-100SC-OR2-C_RO19_EFF02 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.2-18	Botoman G.	2019	Efficacy evaluation of M-100SC-OR2-C in post-	N	Y	Study report never submitted	CIECH

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-18			emergence application against weeds in maize AgroProspect SRL M-100SC-OR2-C_RO19_EFF03 GEP Unpublished			be-fore to Poland	Sarzyna S.A.
KCP 6.4-19	Eberhart A.	2017	Determination of crop safety of Mezotrion 100 SC and Nikosar 060 OD in Corn 2016 Eurofins Agroscience Services Sp. z.o.o S16-02956-01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-20	Eberhart A.	2017	Determination of crop safety of Mezotrion 100 SC and Nikosar 060 OD in Corn 2016 Eurofins Agroscience Services GmbH S16-02960-01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-21	Eberhart A.	2017	Determination of crop safety of Mezotrion 100 SC and Nikosar 060 OD in Corn 2016 AGRITEC, research, breeding and services Ltd S16-02961-01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-22	Eberhart A.	2017	Determination of crop safety of Mezotrion 100 SC and Nikosar 060 OD in Corn 2016 Fyse, Ltd. Dep. Agrolab S16-02962-01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-23	Eberhart A.	2017	Determination of crop safety of Mezotrion 100 SC and Nikosar 060 OD in Corn 2016 Eurofins Agrosience Services S.R.L. S16-02963-01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-24	Eberhart A.	2017	Determination of crop safety of Mezotrion 100 SC and Nikosar 060 OD in Corn 2016 Eurofins Agrosience Services Kft. S16-02964-01 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-25	Krawczuk M.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied post-emergence in maize SGS Polska Sp. z o.o. M-100SC-OR2-C_SEL_PL_1 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-26	Krawczuk M.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied post-emergence in maize SGS Polska Sp. z o.o. M-100SC-OR2-C_SEL_PL_2 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-27	Krawczuk M.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied post-emergence in maize SGS Polska Sp. z o.o. M-100SC-OR2-C_SEL_PL_3 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.

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KCP 6.4-28	Křížek S.	2020	Evaluation of the selectivity of M-100SC-OR2-C applied in maize, Czech Republic, 2019 SynTech Research Czech Republic s.r.o. M-100SC-OR2-C_SEL_CZ_1 GEP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 6.4-29	Šmahel P.	2020	Evaluation of the selectivity of M-100SC-OR2-C applied in maize, Czech Republic, 2019 SynTech Research Czech Republic s.r.o. M-100SC-OR2-C_SEL_CZ_2 GEP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 6.4-30	Hetterich A.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied in maize Hetterich Fieldwork GbR M-100SC-OR2-C_SEL_DE_1 GEP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 6.4-31	Hetterich A.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied in maize Hetterich Fieldwork GbR M-100SC-OR2-C_SEL_DE_2 GEP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 6.4-32	Hetterich A.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied in maize Hetterich Fieldwork GbR M-100SC-OR2-C_SEL_DE_3 GEP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.

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KCP 6.4-33	Hetterich A.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied in maize Hetterich Fieldwork GbR M-100SC-OR2-C_SEL_DE_4 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-34	Barasits T.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied in maize SynTech Research Hungary Kft. M-100SC-OR2-C_SEL_HU_1 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-35	Botoman G.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied in maize AgroProspect SRL M-100SC-OR2-C_SEL_RO_1 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-36	Botoman G.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied in maize AgroProspect SRL M-100SC-OR2-C_SEL_RO_2 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.
KCP 6.4-37	Botoman G.	2019	Evaluation of the selectivity of M-100SC-OR2-C applied in maize AgroProspect SRL M-100SC-OR2-C_SEL_RO_3 GEP Unpublished	N	Y	Study report never submitted be-fore to Poland	CIECH Sarzyna S.A.

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KCP 9.2.4.	Ilona Łożuk	2022	Calculation of the predicted environmental concentrations of mesotrione and its metabolites in groundwater after application of Juzan Extra 100 SC (FOCUS PEARL, FOCUS PELMO, MACRO in FOCUS) CIECH Sarzyna S.A., Poland RR/02/22 non GLP Unpublished	N	N	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 9.2.5.	Siwiec I.	2022	Calculation of the predicted environmental concentrations of mesotrione and its metabolites in surface after application of JUZAN EXTRA 100 SC (STEPS 1-2 in FOCUS, SWASH, SWAN) CIECH Sarzyna S.A., Poland RR/06/22 non GLP Unpublished	N	N	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.1.2 (KCP 5.1.2/01)	Peda T.	2021	Magnitude of residues of Mesotrione in maize (Raw Agricultural Commodity) after one application of M-100SC-OR2-C – four decline curve studies in Poland, Germany, Hungary and Northern France - 2021 No. 21SGS76 SGS Poland, Warszawa GLP, Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.2.1/01 (KCP 5.1.2/08)	Szlauer S.	2022	Daphnia sp., Acute Immobilisation Test according to OECD Guideline No. 202 (2004) Study code: EMI/4/5/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.

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KCP 10.2.1/02 (KCP 5.1.2/09)	Szlauer S.	2022	Fresh Alga and Cyanobacteria, Growth Inhibition Test according to OECD Guideline No. 201 (2011) Study code: EMI/4/2/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.2.1/03 (KCP 5.1.2/06)	Szlauer S.	2022	Fresh Alga and Cyanobacteria, Growth Inhibition Test according to OECD Guideline No. 201 (2011) Study code: EMI/4/3/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.2.1/04 (KCP 5.1.2/07)	Szlauer S.	2022	Lemna sp., Growth Inhibition Test according to OECD Guideline No. 221 (2006) Study code: EMI/4/6/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	Study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.3.1.1/01	Knapik M.	2020	M-100SC-OR2-C Honeybees (Apis mellifera L.), Acute Oral Toxicity Test STUDY CODE: B-86-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.3.1.1/02	Knapik M.	2020	M-100SC-OR2-C Honeybees (Apis mellifera L.), Acute Contact Toxicity Test STUDY CODE: B-87-20 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.

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			GLP Unpublished				
KCP 10.3.1.2/01	Woźniak A.	2020	Honey bee chronic oral toxicity test according to OECD 245 guideline Study code: 0016/0093/E Test item: M-100SC-OR2-C SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.3.1.2/02	Woźniak A.	2020	Chronic toxicity test for honey bee larvae according to OECD GD 239 Study code: 0016/0091/E Test item: M-100SC-OR2-C SORBOLAB Research Laboratory LLC GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.3.2.2/01	Kulec-Płoszczyca E.	2021	An extended laboratory test for evaluating the effects of M-100SC-OR2-C on the parasitic wasp, <i>Aphidius rhopalosiphii</i> (De Stefani-Perez) STUDY CODE: B-52-21 Łukasiewicz Research Network –Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.3.2.2/02	Šklíba J.	2020	Extended GLP laboratory test for evaluating the effects of a test item on the predatory mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) Study code: 20/201 i2L Research Europe s.r.o. GLP	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 10.3.2.2/03	Nácarová J.	2020	Extended GLP laboratory test for evaluating the effects of a test item on the plant dwelling insect <i>Coccinella septempunctata</i> L. (Coleoptera: Coccinellidae) Study code: 20/199 i2L Research Europe s.r.o. GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.3.2.2/04	Šklíba J.	2020	Extended GLP laboratory test for evaluating the effects of a test item on <i>Chrysoperla carnea</i> (Neuroptera: Chrysopidae) Study code: 20/200 i2L Research Europe s.r.o. GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.4.1/01	Swoboda T.	2021	Earthworm Reproduction Test (<i>Eisenia andrei</i>) according to the OECD Guideline for the Testing of Chemicals No. 222 (July 29, 2016) Study code: EMI/4/7/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.4.2./01	Swoboda T.	2021	Collembolan (<i>Folsomia candida</i>) Reproduction Test according to OECD Guideline No. 232 (2016) Study code: EMI/4/1/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.4.2/02	Dec W.	2021	Predatory mite (<i>Hypoaspis</i> (<i>Geolaelaps</i>) <i>aculeifer</i>) Reproduction Test according to the OECD Guideline	N	Y	study report never submitted before to Poland	CIECH Sarzyna

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			No. 226 (2016) Study code: EMI/4/8/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished				S.A.
KCP 10.5	Swoboda T.	2021	Soil Microorganisms: Nitrogen Transformation Test according to the OECD Guideline No. 216 (2000) Study code: EMI/4/11/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.6.2/01 (KCP 5.1.2/04)	Dec W	2021	Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test according to OECD Guideline No. 208 (2006) Study code: EMI/4/10/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.
KCP 10.6.2/02 (KCP 5.1.2/05)	Dec W	2021	Terrestrial Plant Test: Vegetative Vigour Test according to OECD Guideline No. 227 (2006) Study code: EMI/4/9/2021 Ecomelius Institute Sp. z o. o. GLP Unpublished	N	Y	study report never submitted before to Poland	CIECH Sarzyna S.A.

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

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KCA 4.1.2/01	Alferness PL	1999	ZA1296: Liquid Chromatographic Determination with Fluorescence Detection of ZA1296 & 4- (Methylsulfonyl)-2-Nitrobenzoic Acid in Crops after Conversion to 2-Amino-4-(Methylsulfonyl)-Benzoic Acid - A Modification of TMR0643B Zeneca Agrochemicals, Jealott's Hill, United Kingdom, TMR0882B Not GLP, not published Syngenta File No ZA1296/0121	N	N	-	SYN
II, 4.2	Meyers, T.J.and Ryan, J.	1997	ZA 1296: Determination of ZA 1296 and its Metabolite MNBA in Corn by Gas Chromatography with Mass-Selective Detection (WRC-96-163) Zeneca Report No. TMR0689B	N	N	-	SYN
III, 5.2.1.1/02	Bolygo, E.	1996	ZA 1296: Independent Laboratory Confirmation of an Analytical Method for Liquid Chromatographic Determination with Fluorescence Detection of ZA 1296 and 4- (methylsulfonyl)-2-nitrobenzoic acid in Crops after Conversion to 2-amino-4-(methylsulfonyl)- benzoic acid Zeneca Report No. RJ2149B	N	N	-	SYN
II, 4.2.1.1/03	Meyers, T.J. et al.	1998	ZA 1296: Determination of ZA 1296 in milk, eggs and animal products by gas chromatography with mass-selective detection - Addendum (WRC-98-006) Zeneca Report No. TMR0739B ADD	N	N	-	SYN
III, 5.2.1.1/01	Alferness, P.L.	1996	ZA 1296: Liquid Chromatographic Determination with Fluorescence Detection of ZA 1296, 4-methylsulfonyl-2-nitrobenzoic acid and 2-amino-4-methylsulfonyl-benzoic acid in Soil (WRC-96-107) Zeneca Report No. TMR0661B	N	N	-	SYN
II, 4.2.3.1/01	Meyers, T.J.	1997	ZA 1296: Determination of ZA 1296 or a total of ZA 1296 and MNBA in water by gas chromatography with mass selective detection (WRC-97-025) Zeneca Report No. TMR0707B	N	N	-	SYN
II, 4.2.4.1/01	Leung, S.C	1997	ZA 1296: Analytical Method for the Determination of ZA 1296 in Air (WRC-97-069) Zeneca Report No. RR 97-031B	N	N	-	SYN
KCA 6.1	Wiebe, L.A.	1997	ZA 1296: Stability of ZA 1296 and the Metabolite MNBA in Frozen Crops (Interim Report). Zeneca Report No:RR 97-042B INT GLP, Not published	N	N	-	SYN
KCA 6.2.1/01	Wei Y et al	1997	[Cyclohexane-2-14C]ZA 1296: Nature of the Residues in Corn (Zea mays).	N	N	-	SYN

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			Zeneca Agrochemicals Report : RR 96-026B				
KCA 6.2.1/02	Tarr, J.B. et al	1997	[Phenyl-U-14C]ZA 1296: nature of the residues in corn	N	N	-	SYN
KCA 6.6.1	Spillner, C. et al	1997	[Cyclohexane-2-14C]ZA 1296: confined accumulation studies on rotational crops – low rate	N	N	-	SYN
KCA 6.3/01	Barnes J.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1995 (WRC-96-114) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 96-078B GLP, not published Syngenta File No ZA1296/0409	N	N	-	SYN
KCA 6.3/02	Barnes J., Atger J., Wiebe L., Miller M.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in France During 1996 (Postemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-045B GLP, not published Syngenta File No ZA1296/0421	N	N	-	SYN
KCA 6.3/03	Miller M., Griehl T., Wiebe L., Elvira D.	1998	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Preemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-063B GLP, not published Syngenta File No ZA1296/0418	N	N	-	SYN
KCA 6.3/04	Barnes J., Chamier O., Wiebe L., Miller M.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Postemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-048B GLP, not published Syngenta File No ZA1296/0414	N	N	-	SYN
5.8.1.6/01	Callander, R.D.	1996a	MNBA: An Evaluation of Mutagenic Potential Using S.Typhimurium and E.Coli. Zeneca Central Toxicology Laboratory Report No. CTL/P/4955 GLP Not published	N	N	-	SYN
5.8.1	Fox, V	2000a	MNBA: In vitro cytogenetic assay in human lymphocytes Zeneca Central Toxicology Laboratory Report No. CTL/P/6343 GLP Not published	N	N	-	SYN
5.8.1	Clay, P	2000	MNBA: In vivo rat liver unscheduled DNA synthesis assay Zeneca Central Toxicology Laboratory Report No. CTL/SR1028 GLP Not published	N	N	-	SYN
5.8.1	Fox, V	2000b	MNBA: Rat bone marrow micronucleus test	N	N	-	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Zeneca Central Toxicology Laboratory Report No. CTL/SR1043 GLP Not published				
5.8.1.1/01	Robinson, P.	1996	2-Nitro-4-Methylsulfonyl Benzoic Acid: Acute Oral Toxicity to the Rat. Zeneca Central Toxicology Laboratory Report No. CTL/P/5210 GLP Not published	N	N	-	SYN
5.8.1.7/01	Milburn, G.M.	1998	MNBA: 28 Day Oral Toxicity Study in Rats. Zeneca Central Toxicology Laboratory Report No. CTL/P/5578 GLP Not published	N	N	-	SYN
5.8.1	Rattray, N.J	2000	MNBA: 90 day dietary toxicity study in rats Zeneca Central Toxicology Laboratory Report No. CTL/PR1155 GLP Not published	N	N	-	SYN
5.8.1.1.8/02	Elcombe, B.M.	1998b	ZA1296: Effects of MNBA, a metabolite of ZA1296 on p-hydroxy phenyl pyruvate dioxygenase (HPPD) activity. Zeneca Central Toxicology Laboratory Report No. CTL/R/1367 Non-GLP Not published	N	N	-	SYN
5.8.1	Gledhill, A.J	2000	MNBA: Biotransformation in the rat Zeneca Central Toxicology Laboratory Report No: CTL/P/6326 GLP Not published	N	N	-	SYN

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner