FINAL REGISTRATION REPORT
Part A
Risk Management

Product code: **MEZOFLOR 103 SC**

Product names: **MEZOFLOR 103 SC / FLOCORN 103 SC**

Chemical active substances:

Mesotrione, 100 g/l

Florasulam, 3 g/l

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **Synthos Agro Sp. z o.o.**

Submission date: 07/2023

MS Finalisation date: 10/2024, 12/2024, 03/2025

Version history

When	What
07/2023	Initial dRR
10/2024	zRMS assessment of dRR
12.2024	The final Registration Report
01/2025	Additional information in points 3.7.5
03/2025	zRMS assessment of dRR

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PART A
RISK MANAGEMENT

1 Details of the application

This application was submitted by company Synthos Agro Sp. z o.o., ul Chemików 1, 32-600 Oświecim, Poland.
The information, data and assessments provided in Registration Report, Parts B includes assessment of data and information relating to MEZOFLOR 103 SC where that data has not been considered in the EU review. Otherwise assessments for the safe use of MEZOFLOR 103 SC have been made using endpoints agreed in the EU review of mesotrione and florasulam.

1.1 Application background

The application is submitted for registration of plant protection product MEZOFLOR 103 SC in Poland according to art. 33 of Regulation 1107/2009. The product has not been previously evaluated in any country from Central Zone of Europe according to Uniform Principles. The zRMS is Poland.

The application is for the approval of MEZOFLOR 103 SC a suspension concentrate type of formulation (SC) containing 100 g/L of mesotrione and 3 g/L of florasulam for use as a herbicide in maize by professional users.

1.2 Letters of Access

The Applicant has conducted and submitted own studies on MEZOFLOR 103 SC which are sufficient to evaluate of the product.

Letters of access are enclosed.

1.3 Justification for submission of tests and studies

The Applicant has conducted and submitted own studies on MEZOFLOR 103 SC which are sufficient to evaluate of the product. Data protection claims and a list of submitted test reports and study are included in each section of dRR for MEZOFLOR 103 SC and in Part C.

1.4 Data protection claims

All data submitted in Part C are confidential.
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, on all references specified in Sections 1-10 of Part B in the form of " List of data submitted in support of the evaluation".

2 Details of the authorization decision

2.1 Product identity

Product code	**MEZOFLOR 103 SC**
Product name in MS	MEZOFLOR 103SC/ FLOCORN 103 SC
Authorization number	Not applicable – first authorization
Function	Herbicide
Applicant	Synthos Agro Sp. z o.o.
Active substance(s) (incl. content)	Mesotrione – 100 g/l Florasulam – 3 g/l
Formulation type	Suspension concentrate [SC]
Packaging	0.25 l, 0.5 l, 1 l HDPE bottle 0.5 l PE/PA bottle 5 l, 10 l, 20 l HDPE canister 220 l HDPE drum 1000 l HDPE container
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identiy	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

The evaluation of the application for MEZOFLOR 103 SC resulted in the decision to grant the authorization.

Physical and chemical properties:

No data gaps. The phrases “Mix well before use” and “Store below 30°C” should be included in the label.

Metabolism and residues: Uses are accepted

Efficacy section: Mezoflor 103 SC / Flocorn 103 SC can be granted in line to accepted GAP table and label project.

Ecotoxicology section:

Use is accepted for PL. The refinement risk assessment for mammals should be considered by MSs level.

MEZOFLOR 103 SC pose no unacceptable risk to aquatic organisms according to the label with appropriate buffer zone:

-4 m buffer non-spray zone with 4 meter vegetated filter strip.

To protect non-target plants respect an unsprayed buffer zone of 5 m buffer zone and 75 % drift reduction nozzle to non-agricultural land or 10 m buffer zone and 50 % drift reduction nozzle or 15 m buffer zone to non-agricultural land.

The studies for formulation of MEZOFLOR 103 SC for earthworms and *Folsomia candida* and *Hypoaspis aculeifer* with risk assessment was accepted by zRMS only provisionally. The Applicant should complete the calculation the toxicity endpoints based on geometric mean measured concen-

tration with risk assessment. The risk assessment for soil organisms should be considered by MSs level. The new data with toxicity endpoints recalculation and justification that in this case the best solution is to use endpoints based on nominal concentration in risk assessment for soil organisms was provided by Applicant. The recalculation should be treated as additional source information. **In this case, when the concentration values fall below the limit of quantification of the analytical method, it is not possible to determine reliable toxicity endpoints based on geometrically measured concentrations.** The risk assessment for soil organisms, in this case, based on toxicity endpoints based on nominal concentration was accepted by zRMS. No additional data is required.

Identity section: The evaluators also verified whether the co-formulants contained in plant protection product Mezoflor 103 SC are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.
Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product Mezoflor 103 SC does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009.
According to the current knowledge and available information, none of the co-formulants in the plant protection product Mezoflor 103 SC meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products.
Detailed assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574 can be found in RR Part C and annex to Part C of this submission (section 1.2.2).

2.3 Substances of concern for national monitoring

Not relevant.

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, H361d Aquatic Chronic 1, H410

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. **H410 - Very toxic to aquatic life with long lasting effects**
Precautionary statement(s):	**WARNING SECTION OF THE LABEL** (first page): **P202 - Do not handle until all safety precautions have been read and understood.** **P280 - Wear protective gloves, protective clothing** **P308 +P313 - IF exposed or concerned: Get medical advice/attention.** P273 - Avoid release to the environment.

	Other sections of the label: P405 - Store locked up. P501 - Dispose of contents/ container to a hazardous waste collection point or special requirements in accordance with local regulations. And P280 as follows: **Operator:** „*Stosować rękawice ochronne oraz odzież ochronną w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.*" "Wear protective gloves and protective clothing during mixing/loading and during application". **Worker:** „*Stosować rękawice ochronne oraz odzież roboczą podczas wchodzenia na teren poddany zabiegowi*." "Wear protective gloves and work wear during when entering the treated area." **Bystander/Resident:** *Podczas wykonywania zabiegu należy zachować 5 metrową strefę buforową oraz dysze ograniczające znos. Należy umieścić tablicę informacyjną:* „Zakaz wejścia na teren poddany opryskowi do końca uprawy". Keep a 5 meter buffer zone and drift-reduction nozzles during application. Warning board should be placed: "*Do not enter the treated area till the end of the plant growth".* **Section "First aid":** P308 +P313 - IF exposed or concerned: Get medical advice/attention.
Additional labelling phrases:	**To avoid risks to man and the environment, comply with the instructions for use. [EUH401]** **Contains 1,2-benzizotiazol3(2H)-on. May produce an allergic reaction. [EUH208]**

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-benzizotiazol3(2H)-on. May produce an allergic reaction

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).
SPe 3	To protect aquatic organisms respect a: - 4 m buffer non-spray zone with 4 meter vegetated filter strip. To protect non-target terrestrial plants respect a: - 5 m buffer zone and 75 % drift reduction nozzle, - 10 m buffer zone and 50 % drift reduction nozzle, - 15 m buffer zone.

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

Not applicable.

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	gloves and protective clothing
Worker protection:	
respective code if available	wear (arms, body and legs covered) and protective gloves
Integrated pest management (IPM)/sustainable use:	
respective code if available	Additional phrases according to resident and bystander safety should be used on the label of the product. - warning boards preventing from resident/bystander entry into treated area till the end of cultivation, - min. 5-meter buffer zone during spraying - drift-reduction nozzles.
Environmental protection	
SP 1 SPe 3	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). To protect aquatic organisms respect a: - 4 m buffer non-spray zone with 4 meter vegetated filter strip. To protect non-target terrestrial plants respect a: - 5 m buffer zone and 75 % drift reduction nozzle, - 10 m buffer zone and 50 % drift reduction nozzle, - 15 m buffer zone.
Other specific restrictions	
	No other requirements

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

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

2.5.2 Specific restrictions linked to the intended uses

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

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

respective code if available		
Environmental protection:		Relevant for use no.
respective code if available	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters must be adopted	1-3

2.6 Intended uses (only NATIONAL GAP)

GAP , date: 07/2023

PPP (product name/code):	MEZOFLOR 103 SC, FLOCORN 103 SC/ MEZOFLOR 103SC	Formulation type:	SC
Active substance 1:	Mesotrion	Conc. of as 1:	100 g/l
Active substance 2:	Florasulam	Conc. of as 2:	3 g/l
Applicant:	Synthos Agro Sp. z o.o.	Professional use:	☒
Zone(s):	central	Non professional use:	☐
Verified by MS:	-		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Maize	F	**susceptible weeds:** *Capsella bursa-pastoris* *Galinsoga parviflora* *Thlaspi arense* *Matricaria chamomilla* ~~*Matricaria martima*~~ *Anthemis arvensis* ~~*Viola arvensis*~~ ~~*Centaurea cyanus*~~ ~~*Stellaria media*~~ ~~*Geranium pusillum*~~ ~~*Polygonum convolvulus*~~ ~~*Brassica napus*~~ ~~*Persicaria maculosa*~~ **moderate susceptible weeds:** *Chenopodium album* ~~*Echinochloa crus-galli*~~ *Galium aparine* ~~*Solanum nigrum*~~ ~~*Capsella bursa-pastoris*~~ ~~*Galinsoga parviflora*~~ ~~*Thlaspi arense*~~ ~~*Matricaria chamomilla*~~ *Matricaria martima* ~~*Anthemis arvensis*~~ *Viola arvensis* *Centaurea cyanus* *Stellaria media* *Geranium pusillum*	Foliar spraying	BBCH 12-18	1	N/A	1.0 L/ha	Mesotrione 100 g as/ha Florasulam 3.00 g as/ha	200-300 L/ha	Not relevant	**Eff section:** list of accepted weed was modified.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				Polygonum convolvulus *Brassica napus* ~~*Persicaria maculosa*~~ ~~*Amaranthus retroflexus*~~ ~~*Anchusa arvensis*~~ **Medium resistance:** *Echinochloa crus-galli*									

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				susceptible weeds: *Chenopodium album,* *Galium aparine* ~~*Solanum nigrum*~~ *Capsella bursa-pastoris* *Galinsoga parviflora* *Thlaspi arense* *Matricaria chamomilla* *Matricaria martima* *Anthemis arvensis* *Viola arvensis* *Stellaria media* ~~*Geranium pusillum*~~ *Polygonum convolvulus* ~~*Brassica napus*~~ ~~*Persicaria maculosa*~~ ~~*Amaranthus retroflexus*~~ ~~*Anchusa arvensis*~~ **moderate susceptible weeds:** *Echinochloa crus-galli* ~~*Galium aparine*~~ ~~*Solanum nigrum*~~ ~~*Capsella bursa-pastoris*~~ ~~*Galinsoga parviflora*~~ ~~*Thlaspi arense*~~ ~~*Matricaria chamomilla*~~ ~~*Matricaria martima*~~ ~~*Anthemis arvensis*~~ ~~*Viola arvensis*~~ *Centaurea cyanus* ~~*Stellaria media*~~	Foliar spraying	BBCH 12-18	1	-	1.25 L/ha	Mesotrione 125 g as/ha Florasulam 3.75 g as/ha	200-300 L/ha	Not relevant	**Eff section:** list of accepted weed was modified.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				Geranium pusillum ~~*Polygonum convolvulus*~~ *Brassica napus*									

Remarks table heading:

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

Remarks columns:

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

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of homogenous whitish liquid of, with a characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable/has not a flash point up to the boiling point. It has a self ignition temperature of 585°C. In aqueous solution, it has a pH value around 3.48 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a SC formulation.

3.2 Efficacy (Part B, Section 3)

Preliminary studies: Preliminary range-finding tests were not submitted by the Applicant. The active substances of Mezoflor 103 SC / Flocorn 103 SC (product code: Mezoflor 103 SC) – mesotrione and florasulam, are registered and have been commonly used in agricultural practice for many years. So, many efficacy trials are available to evaluate the effectiveness of products containing those active compounds. **Preliminary tests were not necessary in this case in the opinion of Evaluator.**

In Poland this formulation is not registered yet. Applicant did not submitted justification to combine both active ingredients in Mezoflor 103 SC. However, in the opinion of ZRMs such justification in this case is not required. Expecially in case that the presented efficacy trials, of these two compounds (mesotrione and florasulam) demonstarted the activity against studied weeds in maize. Mezoflor 103 SC demonstarted at least comparable control or even higher to the standard reference products used during trials: NOTOS 100 SC (with 100 g/L of mesotrione, used at dose 1,5 l/ha); OSORNO SC (with 100 g/L of mesotrione, used at dose 1,0 l/ha and 1,5 l/ha) and MUSTANG 306 SE (with 6.25 g/L of florasulam + 300 g/L of 2,4-D, used at dose 0,6 l/ha). Therefore, in the opinion of ZRMs the inclusion of proposed amount of florasulam (3 g/L) and mesotrione (100 g/L) in the formulation of Mezoflor 103 SC can be stated as fully justified.

Mezoflor 103 SC / Flocorn 103 SC (product code: Mezoflor 103 SC) – composition of florasulam (3 g/L) and mesotrione 100 g/L) have a very good effectiveness against maize weeds, as shown in the following section.

MED (Minimum Effective Dose): To provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. However, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2).

Mezoflor 103 SC / Flocorn 103 SC (product code: Mezoflor 103 SC) containing florasulam (3 g/L) and mesotrione (100 g/L) was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Mezoflor 103 SC applied at different dose rates was evaluated in 21 eff. trials carried out on maize. Those trials were conducted in one EPPO zones: N-E EPPO zone in Poland during different growing seasons (2020, 2021 and 2022). Following doses were studied during trials: 0,5 l/ha (0.4N), 0,75 l/ha (0.6N), 1,0 l/ha (0.8 N) and 1,25 l/ha (N rate).

Following weeds were studied during trials: VIOAR (10), CENCY (3), STEME (3), GERPU (6), POLCO (9), BRSNW (8), POLPE (2), AMARE (2), LYCAR (2), CHEAL (19), ECHCG (17), GALAP (6), SOLNI (5), CAPBP (6), GASPA (4), THLAR (6), MATCH (3), MATIN / MATMA (12) and ANTAR (3). In all studies – level of infestation was at the acceptable level.

Below, ZRMs presented results for MED dose against Mezoflor 103 SC / Flocorn 103 SC:

Weed	Number of trials	Mean eff. at 0,5 l/ha	Mean eff. at 0,75 l/ha	Mean eff. at 1,0 l/ha	Mean eff at 1,25 l/ha
AMARE	2	67,9%	72,5%	83,0%	92,0%
ANTAR	3	not studied	93,2%	94,6%	95,8%
BRSNW	8	78,8%	72,1%	78,6%	84,6%
CAPBP	6	not studied	84,6%	89,5%	94,3%
CENCY	3	70,4%	65,9%	71,4%	76,5%
CHEAL	19	76,3%	65,1%	77,0%	85,6%
ECHCG	17	71,2%	49,1%	59,9%	71,7%
GALAP	6	77,6%	69,1%	80,7%	87,5%
GASPA	4	81,9%	80,0%	87,8%	91,0%
GERPU	6	not studied	75,8%	80,6%	84,1%
LYCAR	2	not studied	77,7%	81,5%	86,5%
MATCH	3	not studied	70,7%	87,4%	84,0%
MATIN/MATMA	12	77,7%	73,1%	82,2%	89,0%
POLCO	9	78,8%	72,4%	83,3%	91,6%
POLPE	2	78,3%	81,5%	89,2%	95,1%
SOLNI	5	not studied	66,7%	78,9%	88,6%
STEME	3	not studied	78,8%	84,8%	90,1%
THLAR	6	58,8%	81,1%	86,2%	90,9%
VIOAR	10	58,9%	67,6%	78,2%	85,1%

S > 85% eff. **MS** 70-85% eff **MT** 60-70% eff. **T** <60% eff.

Classification marked by colour and eff. of weeds sensitivity according to Polish rules

Trials submitted by Applicant are sufficient for Poland for MED dose. The clear dose responses was observed for the most of studied weed species. The most effective was dose 1,25 l/ha. However, also dose 1,0 l/ha was characterized by good efficiency. So, both of those doses (1.0 and 1,25 l/ha) should be recommended for use to control weeds in maize. The higher dose, should be use in the case of higher infestaion of weeds.

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

- *for dose 0,5 l/ha* – 2 weeds were claassified as a tolerant (THLAR, VIOAR), 1 weed as a moderately tolerant (AMARE) and 9 weeds as moderately susceptible (BRSNW, CENCY, CHEAL, ECHCG, GALAP, GASPA, MATMA/MATIN, POLCO, POLPE). Lack of weeds classified as a sensitive.
- *for dose 0,75 l/ha* – 1 weed was classified as a tolerant (ECHCG), 4 weeds as a moderately tolerant (CENCY, CHEAL, GALAP, SOLNI), 12 weeds as a moderately susceptible (AMARE, BRSNW, CAPBP, GASPA, GERPU, LYCAR, MATCH, MATIN/MATMA, POLCO, POLPE, STEME, THLAR) and 1 weed as a susceptible (ANTAR).
- *for dose 1,0 l/ha* – 1 weed was classified as a tolerant (ECHCG), lack of moderately tolerant weeds, 12 as a moderately sensitive weeds (AMARE, BRSNW, CENCY, CHEAL, GALAP, GERPU, LYCAR, MATIN/MATMA, POLCO, SOLNI, STEME, VIOAR) and 6 as a senstive weeds (ANTAR, CAPBP, GASPA, MATCH, POLPE, THLAR).
- *for dose 1,25 l/ha* – lack of weeds classified as a tolerant and a moderately tolerant, 5 weeds as a

moderately susceptible (BRSNW, CENCY, ECHCG, GERPU, MATCH) and 14 weeds a susceptible weeds (AMARE, ANTAR CAPBP, CHEAL, GALAP, GASPA, LYCAR, MATIN/MATMA, POLCO, POLPE, SOLNI, STEME, THLAR, VIOAR).

For 4 weed species no clear dose response was observed: CENCY, CHEAL, ECHCG and GALAP. For 15 weed species clear dose response was observed (AMARE, ANTAR, BRSNW, CAPBP, GASPA, GERPU, LYCAR, MATCH, MATIN/MATMA, POLCO, POLPE, SOLNI, STEME, THLAR, VIOAR).

Evaluator conclusion: The claimed dose rate is 1,0 – 1,25 l of product/ha. The minimum effective dose were tested in maize through the NE climatic EPPO zone. The range of 1,0 - 1,25 L product/ha gives control of many of the main susceptible weeds in maize. The 1.0 L product/ha rate gives effective control of many susceptible species, whilst higher rates of up to 1,25 L product/ha rate are needed to give optimum control of other species. The dose rate of 1,0 – 1,25 l of product/ha showed the best efficacy in all mentioned above N-E EPPO zone.

Efficacy: All details about efficacy methodology used during efficacy trials are presented above by Applicant. Submitted reports from field trials (21 in total) carried out on maize include a detailed data on soil and field conditions, agro-technological procedures, fore-crop as well as meteorological conditions and technical details of the spraying etc.

Applicant properly presented efficacy results. Applicant wish to register Mezoflor 103 SC / Flocorn 103 SC in PL (product code: Mezoflor 103 SC) in Poland (N-E EPPO zone).

Only trials with greater than 4-5 weeds/m^2 or over 2% ground cover should be taken for assessment. According to EPPO PP 1/226 at least 6 fully supportive results for major weeds and 2 trials for minor weeds should be required. Therefore, based on knowledge of major/minor status of weeds in each country, weeds with insufficient results should be excluded. In Poland, no PPP with mesotrione and florasulam is registered. Mezoflor 103 SC / Flocorn 103 SC will be the first on the Polish market in this formulation and composition. So, acording to Polish rules for major weeds – at least 6 trials are required and for minor weeds – at least 3 weeds.

Submitted efficacy trials are correctly performed according to appropriate EPPO standards. Accepted weed species for Poland (N-E EPPO zone) should be presented to following scale of sensitivity: S (susceptible) > 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) < 60%.

Applicant submitted trials carried out in 2020, 2021 and 2022. Those 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. Appropriate window application, number of applications and water volume was studied during those trials.

In the opinion of ZRMs number of trials for maize is accepted for Poland.

Below, ZRMs presented the assessment for studied weed species in maize:
It is an average efficacy from all assessments made at 7-14 DAT; 24-32 DAT; 37-85 DAT and 98-112 DAT.

Weed	Number of trials	Mezoflor 103 SC at 1,0 l/ha	Mezoflor 103 SCat 1,25 l/ha	Standard reference product			
				Osorno SC at 1,0 l/ha	Osorno SC at 1,5 l/ha	Notos 100 S.C. at 1,5 l/ha	Mustang 306 SL at 0,6 l/ha
AMARE	2	83,0%	92,0%	-	92,5%	90,8%	96,6%
ANTAR	3	94,6%	95,8%	-	97,1%	-	96,3%
BRSNW	8	78,6%	84,6%	77,5%	96,3%	80,1%	71,2%
CAPBP	6	89,5%	94,3%	99,0%	94,3%	-	90,4%
CENCY	3	71,4%	76,5%	-	100%	76,1%	71,7%
CHEAL	19	77,0%	85,6%	95,3%	95,2%	89,7%	82,0%
ECHCG	17	59,9%	71,7%	63,2%	63,8%	87,8%	0,4%
GALAP	6	80,7%	87,5%	72,1%	75,0%	89,7%	90,1%

GASPA	4	87,8%	91,0%	-	-	95,6%	72,1%
GERPU	6	80,6%	84,1%	-	0%	90,8%	71,5%
LYCAR	2	84,1%	88,4%	-	100%	62,5%	82,5%
MATCH	3	87,4%	94,0%	-	-	91,9%	92,3%
MATIN/ MATMA	12	82,2%	89,0%	92,1%	84,5%	92,5%	65,7%
POLCO	9	83,3%	91,6%	89,2%	76,6%	88,8%	89,5%
POLPE	2	89,2%	95,1%	-	-	93,4%	87,1%
SOLNI	5	78,9%	88,6%	91,4%	84,6%	96,1%	92,2%
STEME	3	84,8%	90,1%	91,0%	93,5%	-	92,0%
THLAR	6	86,2%	90,9%	85,8%	97,1%	91,1%	94,0%
VIOAR	10	78,2%	85,1%	84,4%	88,3%	84,7%	48,7%

Some of studied weed species were not characterized by sufficient number of trials and should be deleted from GAP table and label project: ANTAR (major weed: at least 6 trials should be presented, Applicant submitted only 2); **LYCAR** (minor weed: at least 3 trials should be presented, Applicant submitted only 2), **POLPE** (major weed so at least 6 trials should be preented, Applicant submitted only 2), **SOLNI** (major weed, so 6 trials should be presented, Applicant submitted only 5 trials).

Following weed species can be accepted in the GAP table and label project: CHEAL, **ECHCG**, **POLCO** as a major weeds in maize and **ANTAR**, **BRSNW**, **CAPBP**, **CENCY**, **GALAP**, **GASPA**, **GERPU**, **MATCH**, **MATIN/MATMA**, **STEME**, **THLAR** and **VIOAR** as a minor weeds in maize.

Summary: Obtained results were comparable to standard reference product (in most cases, in some cases – were characterized by better or worse efficiency than standards).

The most effective for most studied weed species for post-emergence use on maize was dose 1,0 L/ha (should be use in condition of lower infestation) and dose 1.25 L/ha.

ECHCG – due to long lasting low temperature conditions in the spring, the emergence of this weed was observed later than usually, which translated into the lack of efficacy of the preparations against ECHCG. In this report, the ZRMs only mentioned the low effectiveness or its lack in a few trials (for ex. SH21KU103W; SH21KU104W; SH21KU105W), which was not due to any resistance to herbicide, but rather to the weather conditions.

In Polish label following weeds species can be included:

- ***for maize***

- **Dose 1,0 L/ha**: *Susceptible weeds*: ANTAR, CAPBP, GASPA, MATCH, THLAR; *Moderately susceptible weeds*: BRSNW, CENCY, CHEAL, GALAP, GERPU, MATIN/MATMA, POLCO, STEME, VIOAR; *Tolerant weeds*: ECHCG.
- **Dose 1.25 L/ha:** *Susceptible weeds:* ANTAR, CAPBP, CHEAL, GALAP, GASPA, MATCH, MATIN/MATMA, POLCO, STEME, THLAR, VIOAR*Moderately susceptible weeds:* BRSNW, CENCY, ECHCG, GERPU.

This plant protection product ‘Mezoflor 103 SC / Flocorn 103 SC’ can be used on maize against weed species included in GAP table and label project. Product can be use post-emergence at BBCH 12-18.

During trials different varietes were studied: **for grain:** Farmueller (2 trials), Farmgigant (1 trial), SY-BOOST (2 trials), P8400 (1 trial); **for silage:** Opoka (2 trials), Konkurent (1 trial), Hulk (1 trial), Kurant (1 trial); **and universal varieties both for grain, silage and bioethanol:** LG 31.256 (1 trial), Baobi (1 trial) and **univerasal varieties for grain and silage:** Rosomak (1 trial), P9027 (1 trial), Farmorite (1 trial), Ricardinio (1 trial), Ronaldinio (2 trials), Kentos (1 trial), P8329 (1 trial). **In the opinion of ZRMs, in**

the label should be put an antry: maize grown for grain, silage and bioethanol.

ZRMs accepted proposed by Applicant water volume: 200-300 l/ha. During 20 eff. trials Applicant studied 200 l/ha of water but in one trial (7H-2022_HPwKu-22-50) was studied 300 l/ha.

ZRMs accepted application window: BBCH 12-18. During trials following stage of crop development at application was studied: BBCH 13-16. So, Mezoflor 103 SC / Flocorn 103 SC is recommended for use at the stage of leaf developing (till the stage og 8 leaf developed).

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

According to HRAC classification, mesotrione belongs to group 27, which inhibit phydroxyphenyl pyruvate dioxygenase (HPPD) in the plastoquinone biosynthesis pathway, which converts p-hydroxymethyl pyruvate to homogenisate.
The second active ingredient of MEZOFLOR 103 SC - florasulam belongs to group 2, which inhibit acetolactate synthase (ALS), also called acetohydroxyacid synthase (AHAS), a key enzyme in the biosynthesis of the branched – chain amino acids isoleucine, leucine and valine.

A. Mechanism of resistance

Mesotrione
Due to very low number of resistance weeds reported to HRAC group 27, reports of resistance are currently limited, and the mechanism of resistance for these biotypes is unknown and as yet unclassified.

Florasulam
The mechanism of resistance in herbicide belongs to HRAC group 2 (ALS resistance) in dicotyledonous weeds is mainly due to Target Site Resistance (TRS), which results from changes in the ALS enzyme. So far, evolved resistance to ALS inhibitors has been associated principally to TSR by one or more point mutations in the nuclear ALS gene, that disrupt herbicide binding and then reduce the sensitivity of the target enzyme to herbicides. Nowadays, 29 amino acid substitutions at eight different positions, namely AL_{122}, Pro_{197}, AL_{205}, Asp_{376}, Arg_{377}, Trp_{574}, Ser_{653} and Gly_{654} have been documented in 165 weed species around the world. These amino acid substitutions results in various cross-resistance patterns among the five chemical families of ALS-inhibiting herbicides depending on weed species.[1]

B. Evidence of resistance

Mesotrione
According to The International Survey of Herbicide Resistand Weeds (http://www.weedscience.com) there are only three species that show resistance to mesotrione worldwide: *Raphanus raphanistrum, Amaranthus tuberculatus* and *Amaranthus palmeri*. At the time of writing this dossiere there were 13 reported cases of resistance to mesotrione: 5 of *Amaranthus palmeri*, 6 of *Amaranthus tuberculatus* and 2 of *Raphanus raphanistrum*. Nine of these cases occurred in the United States between 2009 to 2020, and last two in Australia between 2015 to 2020. In 3 of these cases there were also resistance to other members of 27 class of herbicides (tembotrione, topramezone). In 10 of these cases there was also resistance to other groups of herbicides: auxin mimics (HRAC Group 4), inhibition of acetolactate synthase (HRAC Group 2), inhibition of enolpyruvyl shikimate phosphate synthase (HRAC Group 9), PSII inhibitiors-serine 264 binders (HRAC Group 5), very long-chain fatty acid synthesis inhibitors (HRAC Group 15), phytoene

[1] Hada Z, Menchari Y, Rojano-Delgado AM, Torra J, Menendez J, Palma-Bautista C, de Prado R and Souissi T (2021) Point Mutations as Main Resistance Mechanism Together With P450-Based Metabolism Confer Broad Resistance to Different ALS-Inhibiting Herbicides in Glebionis coronaria From Tunisia. Front. Plant. Sci. 12:626702.

desaturase inhibitors (HRAC Group 12), inhibition of hydrohyphenyl pyruvate dioxygenase (HRAC Group 27).

Florasulam

Resistant weed populations against HRAC group 2 herbicides have been documented worldwide. The majority of cases of resistance have been documented in Northern America. In Poland, about 10 resistance case have been documented. Among these weeds, the following species can be mentioned: *Conyza canadensis, Aspera spica-venti, Alopecurus myosuroides, Centaurea cyanus, Aspera spica-venti, Avena fatua, Alopecurus myosuroides, Tripleurospermum perforatum, Papever rhoeas, Matricaria recutita*. Resistance cases associated with the active ingredient florasulam has been found in *Alopecurus myosuroides* (Netherlands and Denmark), *Amaranthus retroflexus* (Canada and Ukraine), *Aspera spica-venti* (Germany and Denmark), *Capsella bursa-pastoris* (Denmark), *Diplotaxis erucoides* (Israel), *Eucaria hispanica* (Israel), *Lithospermum arvense* (China), *Lolium perenne ssp. Multiflorum* (Denmark), *Lolium rigidum* (Israel), *Matricaria recutita* (Sweden), *Paper rhoeas* (Belgium, Italy, Greece, Denmark, Germany), Polygonum convolvulus (Canada), Rapistrum rugosum (Iran), Rumex dentatus (Indie), *Rumex obtusifolius* (France), *Senecio vulgaris* (France), *Sinapis arvensis* (Italy), *Spergula arvensis* (Norway), *Stellaria media* (United Kingdom, Denmark, France, Sweden, Germany), *Tripleurospermum perforatum / T. inodorum* (Sweden, Denmark, Czech Republic).

According to the HRAC database, worldwide cases of resistance against herbicides of HRAC class 2 are recorded for 169 different weed species. This group includes both monocotyledonous and dicotyledonous weeds. In the case of the GAP use of MEZOFLOR 103 SC there is only one species of monocotyledonous weeds - *Echinochloa crus-galli*. The rest of the proposed weeds in GAP use of MEZOFLOR 103 SC belongs to dicotyledonous weeds. Although monocotyledonous weeds are believed not to be susceptible to florasulam, the monocotyledonous weed identified in GAP is susceptible to the second active ingredient - mesotrione. Resistance case in monocotyledonous weeds are mainly relevant for other chemical groups, including imidazolinone, sulfonylurea, sulfonylaminocarbonyl-triazolinone and imidazolinone pyrimidinyl(thio)benzoate.

C. Cross resistance

Cross-resistance is defined as the ability of a weed population to express resistance to more than one herbicide. There are two type of cross resistance: across herbicide subgroups – this occurs when a weed population is resistant to more than one herbicide subgroup within a specific mode of action group, and second type – across herbicide mode of action groups - this occurs when a weed population is resistant to herbicides from within more than one mode of action group.

Mesotrione

As it was mentioned in chapter "Evidence of resistance", cross-resistance has occurred within 11 of the 13 reported cases of resistance to mesotrione and within the biotypes of all classified weed species (*Amaranthus palmeri, Amaranthus tuberculatus* and *Raphanus raphanistrum*). Therefore, there is some slight potential within weed populations for cross-resistance to occur to other modes of action, including the inhibition of acetolactate synthase of which florasulam (second active substance of MEZOFLOR 103 SC) is a member. Cross – resistance for inhibition of acetolactate synthase has also been reported, however no cases have been found in Europe of cross-resistance to either florasulam or mesotrione.

Florasulam

ALS resistance which is the major resistance mechanism in HRAC group 2 is mainly due to Target Site Resistance (TSR), ensuing from changes in the ALS enzyme conferred to a point mutation. As it was mentioned, with respect to the active substance florasulam worldwide 33 resistance cases have been reported for 20 different weed species. In the majority of cases cross resistance has been reported to ALS

inhibitors (HRAC Group 2) herbicides. In four cases multiple site of action resistance was reported in the HRAC database for *Alopecurus myosuroides* (Denmark), *Apera spica-venti* (Denmark), *Lolium perenne ssp. multiflorum* (Denmark), *Lolium rigidum* (Israel). However, as monocotyledons species usually are not sensitive to florasulam the conclusions for multi-site resistance in this grass weed are considered to be of low relevance.

D. Multiple resistance

Multiple resistance is a term used to describe weed populations that exhibit more than one resistant mechanism, allowing the plant to withstand herbicides from different subgroups. This type of resistance is more important than cross resistance from the practical point of view.

Mesotrione

In the case of all the listed species, the phenomenon of multiple resistance also occurred. However, all these cases have so far occurred outside the European Union. Nevertheless, every effort should be made to prevent the phenomenon from occurring.

Florasulam

According to weedscience.org there are few cases of multiple weeds resistance to ALS inhibitors (HRAC Group 2): *Alopecurus aequalis, Alopecurus japonicus, Alopecurus myosuroides, Amaranthus blitoides, Amaranthus hybridus, Amaranthus palmeri, Amaranthus powellii, Amaranthus retroflexus, Amaranthus tuberculatus, Amaranthus viridis, Ambrosia artemisiifolia, Ambrosia trifida, Apera spica-venti, Arctotheca calendula, Avena fatua, Avena sterilis, Avena sterilis ssp. Ludoviciana, Bidens pilosa, Bidens subalternans , Brassica rapa (=B. campestris), Chloris radiata , Conyza canadensis , Conyza sumatrensis , Cynosurus echinatus, Digitaria sanguinalis , Echinochloa colona, Echinochloa crus-galli var. crus-galli, Echinochloa crus-galli var. formosensis, Echinochloa oryzoides, Echinochloa phyllopogon (=E. oryzicola), Euphorbia heterophylla, Galium aparine, Galium spurium, Hirschfeldia incana, Ischaemum rugosum, Kochia scoparia, Limnocharis flava, Limnophila erecta, Lolium perenne Lolium perenne ssp. Multiflorum, Lolium rigidum, Papaver rhoeas, Phalaris brachystachys, Phalaris minor, Phalaris paradoxa, Poa annua, Ranunculus acris, Raphanus raphanistrum, Sagittaria montevidensis, Senecio vernalis, Sinapis arvensis, Sisymbrium orientale, Sorghum halepense,*

Out of these, there are some species of weeds with the indicated multiple resistance of potential interest in this submission*: Echinochloa crus-galli, Galium aparine, Amaranthus retroflexus, Sinapis sp.* However, the most important things is to notify that there are no cases of multiple resistance relative to ALS inhibitors (HRAC Group 2) group founds in Poland up to date.

Due to the fact, that the cross resistance and multiple resistance, as well as resistance is a very dynamic ongoing proces and the major prevention strategy is this – included in Good Agricultural Practise and Integrated Pest Management strategies with avoidance of sequential use of herbicides belonging to the same SOAs and cross resistant groups.

E. Sensitivity data

It is obvious that pests vary in their sensitivity both between and within populations, and this natural variation occurs and may have an influence on the weeds sensitivity assessment.

Mesotrione

Mesotrione is existing active substance and have been used for many years across the EU, baseline sensitivity of MEZOFLOR 103 SC to weeds cannot be established beyond the data provided in this dossier. In the supporting effectiveness studies many of the target weeds were shown to be moderately tolerant to highly sensitive to MEZOFLOR 103 SC with no large variations in levels of control that could suggest the occurrence of resistant biotypes.

Florasulam

For the active substances: florasulam - no baseline sensitivity studies were available to the applicant. The overview of the Herbicide Resistance Action Committee (HRAC) about the evidence of resistance can replace baseline sensitivity studies. Moreover, submission of sensitivity data is not considered to be required due to the following reasons:

- the long time of using herbicides from the HRAC 2 group makes it impossible to obtain real data on the sensitivity of weeds to substances from this group,
- limited number of florasulam resistance within in the Central EU Zone despite more than ten years of use.

In addition, basic data on the sensitivity of weeds to substances from the HRAC 2 group can be inferred from product registration within Central EU Zone. Herbicidal products based on the active ingredient florasulam have been introduced to the market in 1999. However, despite the lack of data on the sensitivity of weeds to the active substance florasulam obtained prior to the use of this substance, it can be concluded that the levels of sensitivity and variability are well documented in the field trials provided in the registration dossiers submitted to obtain registration of the first products in the EU.

Sensitivity data should be generated and available in the future to measure sensitivity shift and resistance development.

Since the resistance risk of the uses of MEZOFLOR 103 SC could be considered to be medium, the implementation of a special management strategy is required. General principles of Good Agricultural Practices and Good Plant Protection Practices are the basis of the weed management strategy:

- select the correct active ingredient and product for the situation.
- follow label recommendations, particularly to ensure the treatment is made at the correct weed growth stage, under suitable climatic conditions and at the correct dosage. The minimum required dose should be applied but further dose reductions should be avoided since they can encourage a shift to tougher weed species. Timing of the application can be critical for perennial weeds, and it may be necessary to change the season of application each year to prevent a shift to species which are less susceptible at certain times of year.
- optimize the use of the range of agronomic tools to manage weed growth which are part of normal croor landscape management programmes. For example, crop rotation and cultivation or in non-crop areas such as roadsides, road and pavement sweepers. minimize the risk of spreading weed infestations. Ensure farm equipment is clean of soil and vegetation when moving between fields. Avoid introducing weeds seeds by using certified seed.
- Where necessary mow/spray non-crop vegetation adjacent to field to prevent seed production. Good spraying practice should always be followed to attain effective weed control:
- spray equipment must be checked periodically (e.g. by authorized people).
- dose and spray accurately- calibrate the sprayer and make the correct amount of spray mix for the area to be treated.
- use the correct nozzles to maximize coverage of the weeds with minimum spray drift
- apply only under appropriate weather conditions, e.g. weeds are not stressed due to high temperatures, frost, drought or waterlogging.
- no rainfall falls during application or within two hours after application.
- suitable wind speed.
- monitor the weed control during the cropping season and look out for potential problems before they arise.

In the opinion of ZRMs due to the different mode of action of both active substances: mesotrione and florasulam, the occurrence of resistance to this herbicide is medium.

For the use of Mezoflor 103 SC / Flocorn 103 SC (product code: Mezoflor 103 SC) against target weeds it can be concluded, that:

- The product has a low to medium inherent and agronomical risk for resistance weed development.
- To decrease the risk of selecting resistant weeds, the application of an additional herbicide belonging to a different mode of action and having high efficacy on the species to be controlled is recommendable.
- It is recommended to use the product in alternation or in combinations with compounds having a different mode of action.
- To avoid the selection of resistance it is recommended to perform one application of Mezoflor 103 SC / Flocorn 103 SC at the recommended dose(s) per season.

Also, for minimize the risk of occurrence and development of herbicide weed resistance we should follow Good Agricultural Practice.

In our opinion the risk for florasulam nad mesotrione in Mezoflor 103 SC / Flocorn 103 SC (product code: Mezoflor 103 SC) can be defined as medium. Applicant submitted detailed information's about possibilities of development the resistance or cross-resistance. Evaluator accepted the strategy management about possible development of resistance or cross-resistance proposed by Applicant

The abidance of the requirements within the good agricultural practice is necessary. The resistance management is coordinated by HRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

3.2.2 Adverse effects on treated crops

During the experiment, the effect of phytotoxicity on MEZOFLOR 103 SC and the impact on non-target organisms were observed.
MEZOFLOR 103 SC containing the well-known active ingredients mesotrione and florasulam, is intended for use as a selective herbicide. Assessment of phytotoxicity was performed in accordance with EPPO guidelines: PP 1/181(4), PP 1/181(5), PP 1/152(4), PP 1/135(4) and PP 1/50(3).

In the evaluation process the fact that the active ingredients – mesotrione and florasulam are used in many plant protection products and has been commonly used in crop protection were taken into consideration by Evaluator. However, in Poland – no PPP with both of those a.s. is already registered.
The Applicant submitted in total 6 selectivity studies carried out on maize. Those trials were performed in one EPPO zone – N-E in Poland during two growing seasons (2020 and 2021) on different varietes (Farmoso, Farmezzo, KWS Kwintus, Hulk, Opoka, SY Talisman). Two of studied vatietes of maize are for grain (SY talisman and KWS Kwintus) and four for silage (Farmoso, Farmezzo, Hulk. Opokoa). Studies were condacted in different provinces: wielkopolskie (4 trials), pomorskie (1 trial) and dolnośląskie (1 trial). Methodology was in line to EPPO standard. Valid plot area was used ($21m^2$ – 3 trials, 24 m^2 – 1 trial and $33m^2$ -2 trials). In the opinion of ZRMs submitted documentation is sufficient for N-E for Poland in line to GAP table.
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 assessment was carried out with the use of different cultivars (commercially grown varieties). Dosages N (recommended) and 2N (doubled recommended) were studied during selectivity trials. Experimental details and assessments methods were in accordance to EPPO standards.

No phytotoxicity symptom caused by MEZOFLOR 103 SC at the highest dose rate of 2.5 L/ha was recorded in all trials. No signs of phytotoxicity effects were observed in all trials. Phytotoxicity in all tested samples was 0%. All results were comparable to standard reference product.
In the opinion of ZRMs it can be concluded that Mezoflor 103 SC / Flocorn 103 SC is safe for use on maize at recommended dose.

Effect on the yield: Effects of Mezoflor 103 SC / Flocorn 103 SC on yield of maize were assessed during 6 selectivity trials. In those studies yield was assessed after application of single, highest rate (1,25 L/ha for Mezoflor 103 SC) of above product as well as twice the highest rate (2,50 l/ha). Statistical analysis of yield and its parameters was done. All results were comparable to standard reference product (Osorno SC – 2 trials and Notos 100 SC – 4 trials).Yield was assessed at BBCH 85-87 in 2 trials and BBCH 99 in 4 trials.

No significant adverse effect on maize was observed after application of Mezoflor 103 SC / Flocorn 103 SC in comparison to the control.

Below, ZRMS presented detailed results for yield:

- ***maize***

Report No.		119-SYNT-FH21KU109W	120-SYNT-FH21KU110W	277-01-F20-477	277-02-F20-478	SGS/2021/074/PL01	SGS/2021/074/PL02
Product	**Dose per h**	***t/ha***	***t/ha***	***t/ha***	***t/ha***	***t/ha***	***t/ha***
Control	-	10,970 a*	11,215 a*	11,03 a	7,61 a	7,98 a	9,77 a
Mezoflor 103 SC	1,25 l	10,853 a	9,880 a	10,88 a	7,63 a	8,29 a	9,72 a
Mezoflor 103 SC	2,50 l	11,265 a	10,813	10,79 a	7,71 a	8,16 a	9,86 a
Osorno SC	1,50 l	10, 903 a	10,550	-	-	-	-
Osorno SC	3,00 l	11,790 a	11,143	-	-	-	-
Notos 100 SC	1,50 l	-	-	11,07 a	7,72 a	8,19 a	9,87 a
Notos 100SC	3,00 l	-	-	11,09 a	7,46 a	8,14 a	9,84 a

* Values in columns followed by the same letter do not differ significantly at p=0,05

In field trials on maize Mezoflor 103 SC was used in single rate of 1,25 L/ha and doubled rate of 2,5 L/ha, did not have significant adverse effect on yield. Phytotoxicity effects were not observed, even on the plots where double rate was used. No statistical differences in yield were observed between plots treated with Mezoflor 103 SC as well as on control plots.

Effect on the quality of yield: No significant adverse effect on maize was observed after application of Mezoflor 103 SC in comparison to the control. **It can be concuded that Mezoflor 103 SC have no negative impact on the quality of maize yield.**

Below, ZRMS presented detailed results for quality of yield:

- ***moisture [%]***

Report No.		119-SYNT-FH21KU109W	120-SYNT-FH21KU110W	277-01-F20-477	277-02-F20-478	SGS/2021/074/PL01	SGS/2021/074/PL02
Product	**Dose per h**	***Moisture [%]***	***Moisture [%]***	***Moisture [%]***	***Moisture [%]***	***Moisture [%]***	***Moisture [%]***
Control	-	24.80 ab	25,40 a	22,05 a	30,75 a	31,1 a	36,7 a
Mezoflor 103 SC	1,25 l	24,53 b	28,20 a	22,45 a	30,75 a	31,6 a	36,6 a
Mezoflor 103 SC	2,50 l	26,93 a	27,68 a	22,83 a	30,53 a	31,5 a	36,4 a
Osorno SC	1,50 l	26,30 ab	27,43 a	-	-	-	-
Osorno SC	3,00 l	25,50 ab	26,43 a	-	-	-	-
Notos 100 SC	1,50 l	-	-	22,63 a	30,78 a	31,8 a	36,2 a
Notos 100SC	3,00 l	-	-	22,68 a	30, 88 a	31,3 a	36,5 a

* Values in columns followed by the same letter do not differ significantly at p=0,05

In all trials no negative effects on the moisture [%] was recorded at the proposed dose rate and at the double dose rate. No statistical differences were observed between untreated and treated fields and also between the tested product and the standard products. Only in one trial (119-SYNT-FH21KU109W) significant differences were recorded. During this trial the lowest moisture was noted in the control and Mezoflor 103 SC used at N dose (1,25 l/ha). The highest moisture was at 2N dose of Mezoflor 103 SC.

– ***protein [%]***

Report No.		119-SYNT-FH21KU109W	120-SYNT-FH21KU110W	277-01-F20-477	277-02-F20-478	SGS/2021/074/PL01	SGS/2021/074/PL02
Product	**Dose per h**	***Protein [%]***	***Protein [%]***	***Protein [%]***	***Protein [%]***	***Protein [%]***	***Protein [%]***
Control	-	12,03 a	11,65 a	-	-	-	-
Mezoflor 103 SC	1,25 l	12,08 a	12,28 a	-	-	-	-
Mezoflor 103 SC	2,50 l	12,33 a	12,35 a	-	-	-	-
Osorno SC	1,50 l	12,75 a	12,23 a	-	-	-	-
Osorno SC	3,00 l	12,33 a	11,70 a	-	-	-	-
Notos 100 SC	1,50 l	-	-	-	-	-	-
Notos 100SC	3,00 l	-	-	-	-	-	-

* Values in columns followed by the same letter do not differ significantly at p=0,05

In all trials no negative effects on the protein content [%] was recorded at the proposed dose rate and at the double dose rate. No statistical differences were observed between untreated and treated fields and also between the tested product and the standard products.

– ***starch [%]***

Report No.		119-SYNT-FH21KU109W	120-SYNT-FH21KU110W	277-01-F20-477	277-02-F20-478	SGS/2021/074/PL01	SGS/2021/074/PL02
Product	**Dose per h**	***Starch [%]***	***Starch [%]***	***Starch [%]***	***Starch [%]***	***Starch [%]***	***Starch [%]***
Control	-	67,85 a	68,93 a	44,40 a	44,63 a	-	-
Mezoflor 103 SC	1,25 l	68,06 a	68,55 a	44,75 a	45,03 a	-	-
Mezoflor 103 SC	2,50 l	67,88 a	68,40 a	44,40 a	43,58 a	-	-
Osorno SC	1,50 l	67,83 a	68,35 a	-	-	-	-
Osorno SC	3,00 l	67,65 a	68,80 a	-	-	-	-
Notos 100 SC	1,50 l	-	-	44,38 a	43,70 a	-	-
Notos 100SC	3,00 l	-	-	44,28 a	43,68 a	-	-

* Values in columns followed by the same letter do not differ significantly at p=0,05

In all trials no negative effects on the starch content [%] was recorded at the proposed dose rate and at the double dose rate. No statistical differences were observed between untreated and treated fields and also between the tested product and the standard products.

– ***oil [%]***

Report No.		119-SYNT-FH21KU109W	120-SYNT-FH21KU110W	277-01-F20-477	277-02-F20-478	SGS/2021/074/PL01	SGS/2021/074/PL02
Product	**Dose per h**	***oil [%]***	***oil [%]***	***oil [%]***	***oil [%]***	***oil [%]***	***oil [%]***
Control	-	4,15 ab	4,40 a	-	-	-	-
Mezoflor 103 SC	1,25 l	3,93 b	4,48 a	-	-	-	-
Mezoflor 103 SC	2,50 l	4,23 a	4,53 a	-	-	-	-
Osorno SC	1,50 l	4,20 ab	4,43 a	-	-	-	-
Osorno SC	3,00 l	4,28 a	4,38 a	-	-	-	-
Notos 100 SC	1,50 l	-	-	-	-	-	-

Notos 100SC	3,00 l	-	-	-	-	-	-

* Values in columns followed by the same letter do not differ significantly at p=0,05

Oil content [%] was studied during two trials. In one trial – 119-SYNT-FH21KU109W significant differences were noted. The highest oil content [%] was reported in maize treated by Mezoflor 103 SC at 2N dose and st. ref. product at 2N dose. Sligtly lower content of oil was noted in the control and maize treated by st. ref. product at N dose. The lowest oil content was in maize treated by Mezoflor 103 SC at N dose. In the second trial – 120-SYNT-FH21KU110W no differences were noted.

– ***thousand grain weight [g]***

Report No.		**119-SYNT-FH21KU109W**	**120-SYNT-FH21KU110W**	**277-01-F20-477**	**277-02-F20-478**	**SGS/2021/074/PL01**	**SGS/2021/074/PL02**
Product	**Dose per h**	***TGW [g]***	***TGW [g]***	***TGW [g]***	***TGW [g]***	***TGW [g]***	***TGW [g]***
Control	-	325,435 a	336,965 a	-	-	341,12 a	346,36 a
Mezoflor 103 SC	1,25 l	340,875 a	311,693 a	-	-	341,05 a	346,42 a
Mezoflor 103 SC	2,50 l	347,885 a	329,718 a	-	-	340,91 a	346,15 a
Osorno SC	1,50 l	323,986 a	334,380 a	-	-	-	-
Osorno SC	3,00 l	345,598 a	332,290 a	-	-	-	-
Notos 100 SC	1,50 l	-	-	-	-	353,67 a	345,97 a
Notos 100SC	3,00 l	-	-	-	-	341,10 a	346,21 a

* Values in columns followed by the same letter do not differ significantly at p=0,05

In all trials no negative effects on the thousand grain weight [g] was recorded at the proposed dose rate and at the double dose rate. No statistical differences were observed between untreated and treated fields and also between the tested product and the standard products.

3.2.3 Observations on other undesirable or unintended side-effects

Effect on the transformation processes: In the section B7 is presented following information:

- *The level of florasulam residue in cobs and grains is below the limit of quantificatiin (< 0,01 mg/kg). Further ivestigation on florasulam residues in processed commodities is not required*.
- *The level of mesotrione residues in forage, silage and grain is below the limit of quantification (< 0.01 mg/kg). Further investigation on mesotrione residues in processed commodities is not required.*

The applicant presented no data on effects on transformation processes taking note that there are no major transformation processes applicable to forage or grain maize, products containing mesotrione or florasulam as the sole active substance or together in co-formulations have been approved and extensively used as herbicides in maize across EU countries for many years and are well proven to have no negative impact on any relevant processing procedures. So, lack of data can be acceptable. **No negative effects on transformation processes are expected.**

Impact on propagation: ZRMS accepted Applicant statement for lack of trials against propagation. Mezoflor 103 SC / Flocorn 103 SC (product code: Mezoflor 103 SC), similarly, to the references products to which was compared, has shown to be selective to treated crops, showing negligible phytotoxicity symptoms and with no effect on yield at the N dose. Therefore, no further data is deemed to be necessary in the opinion of Evaluator.

Also, products containing mesotrione or florasulam have been using for many years and have been proven not to have a negative effect on the viability of progeny seed. So, it can be stated that **no negtive effect on propagating purposes is expected.**

Impact on succeeding crops: The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops.

Therefore, the Applicant should present the assessment of the possible effect of Mezoflor 103 SC on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance to the EPPO Standard Efficacy evaluation of plant protection products.

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.

Components of Mezoflor 103 SC are old active ingredients (florasulam, mesotrione) authorised for maize production for long time ago. So, restrictions on rotational crops are well-known. According to the scientific data half dissipation time (DT_{50}) of mesotrione is 4.5 to 32 days (related to soil pH, getting shorter as soil pH rose) and DT_{50} for florasulam is 2-18 days. So, it can be assumed that the herbicide Mezoflor 103 SC / Flocorn 103 SC (product code: Mezoflor 103 SC) is degraded in the soil during the growing season to a level that does not pose a risk to succeeding crops.

ZRMs agree with Applicant that According to intended GAP, MEZOFLOR 103 SC will be apply at the latest in BBCH 18 in maize. There will be about 3-4 months until harvest of the crop, and at least about 5-6 months before succeeding crop will be sown. Ploughing the crop prematurely after the use of mesotrione and florasulam due to crop failure (e.g. damage by winterkilling) can be excluded since such a decision should have been taken already before spraying the herbicide to control the weeds in maize.

However, in line to Ecotoxicilogy section, some security steps should be added to label. What is improtant this step is already included in registered PPPs with mesotrione, so to the opinion of zRMS this label information must be retained:

„Under extremely unfavourable conditions (sandy soils, soils that dry out easily, soils with a low pH [<6.0], soils with a high organic matter content [>4.0%], low biological activity, exceptionally low winter temperatures, exceptionally low soil moisture in summer and/or autumn and/or winter, overlapping of the sprayed area, excessively compacted soil), temporary bleaching, stunted growth and reduced plant populations may occur in sensitive crops (beets, legumes, sunflowers and vegetables). It is therefore not recommended to grow the above crops as follow-on crops if the soil pH is significantly below 6.0 or if there has been a prolonged drought following the previous season's application. Ploughing to a minimum depth of 15 cm after maize and a soil pH above 6.0 will significantly reduce the risk of damage to these crops.

If a treated field has to be ploughed beforehand (due to crop damage by frost, disease or pests), only maize or perennial ryegrass may be grown on the same field after pre-sowing. After ploughing to a depth of min. after ploughing to a depth of at least 15 cm, sorghum may be grown in addition to the above crops.

Winter rape can only be sown in the autumn of the following year, as can sugar beet (in the spring of the year following the last application).

After harvesting maize grown for grain and silage under normal growing conditions, cereals can be grown:

- in autumn, winter cereals and winter oilseed rape and Brassica vegetables. Plough to a minimum depth of 15 cm before sowing winter oilseed rape and brassica vegetables. 15 cm.

- in spring - maize (grain and silage) and spring wheat and barley”

Impact on adjacent crops: The Mezoflor 103 SC / Flocorn 103 SC (product code Mezoflor 103 SC) is effective against some mono- and dicotyledonous weeds. In this situation, this plant protection product may also cause discoloration and damage to non-target foliage plants, including adjacent crops. The information in this registration report and label warns against overlapping and drift of the spray liquid should be presented.

Therefore, warnings to avoid spray drift on adjacent crops should appear on the label. For example: *During spraying, maintain a safety zone of at least 5 m from residential buildings/habitats and members of the public. When spraying, use drift reduction techniques (drift resistant nozzles, low vehicle speed, stable weather, etc.).*

Effect on beneficial and other non-target organisms: Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Ecotoxicology section. However, accordingly to documentation submitted by Applicant (efficacy and selectivity trials) – none negative effect was observed on non-target organisms during all trials.

3.3 Methods of analysis (Part B, Section 5)

It was confirmed that chromatographic methods of determination of the active compounds (mesotrione and florasulam) are specific. No interference was observed. The validation parameters (linearity, LOQ, repeatability and accuracy) are within the acceptance range and fulfil EU requirements given in SANCO/3030/99 rev.5 and SANTE 12830/2020.
It was confirmed that chromatographic methods of determination of the relevant impurities (IMP1, IMP2, 2,6-DFA and 1,2-dichloroethane) are specific. No interference was observed. The validation parameters (linearity, LOQ, repeatability and accuracy) are within the acceptance range and fulfil EU requirements given in SANCO /3030 /99 rev. 5.

3.3.1 Analytical method for the formulation

With respect to toxicological, eco-toxicological or environmental aspects MEZOFLOR 103 SC does not contain any relevant formulants. Therefore, a special analytical method and validation is not needed.

3.3.2 Analytical methods for residues

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

Commodity/crop	Supported/ Not supported
Maize	Supported

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD_{50} oral, rat (calculation method)	(>) 2000 mg/kg bw	Yes	None	Additivity formula (calculation method)
	Not submitted, not necessary. Justification presented in **Błąd! Nie można odnaleźć źródła odwołania.**			
LD_{50} dermal, rat (calculation method)	-	Yes	None	Additivity formula (calculation method)
	Not submitted, not necessary. Justification presented in **Błąd! Nie można odnaleźć źródła odwołania.**			
LC_{50} inhalation, rat (calculation method)	-	Yes	None	Additivity formula (calculation method)
	Not submitted, not necessary. Justification presented in **Błąd! Nie można odnaleźć źródła odwołania.**)			
MEZOFLOR 103 SC: *In Vitro* Skin Corrosion: Reconstructed Human Epidermis Test Method (OECD 431)	Non-irritant	Yes	None	Krakowian D., 2021
MEZOFLOR 103 SC: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage (OECD 438)	Non-irritant	Yes	None	Krakowian D., 2021
Skin/resporatory sensitisation (calculation method)	Non-sensitising	Yes	None	Additivity formula (calculation method)
	Not submitted, not necessary. Justification presented in **Błąd! Nie można odnaleźć źródła odwołania.**.			
Supplementary studies for combinations of plant protection products	No data – not required			

MEZOFLOR 103 SC does not contain any substances classified as:

- respiratory sensitizer,
- germ cell mutagenic,
- cancerogenic,

- toxic on specific target organs (single exposure),
- aspiration hazard.

MEZOFLOR 103 SC is classified as Repr.2 (H361d).

3.4.2 Operator exposure

According to the results of exposure estimations, the use of MEZOFLOR 103 SC containing mesotrione (100 g/L) and florasulam (3 g/L) causes acceptable health risk for protected operator (work wear, protective gloves during mixing&loading and application).
Consequently, the following sentence regarding the use of PPE is recommended by the evaluator to be placed in the label:

„*Stosować rękawice ochronne oraz odzież ochronną w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.*"
"Wear protective gloves, and protectiv clothing during mixing/loading and during application".

3.4.3 Worker exposure

According to the results of the estimations, the use of MEZOFLOR 103 SC does not cause unacceptable health risk for a worker wearing work and protective gloves according to EUROPOEM II.
The results of estimations using EFSA model for mesotrione indicate unacceptable health risk for operator equipped only with work wear (no gloves).

Bearing in minds the results of exposure assessment (EUROPOEM II), the following sentence regarding the use of PPE should to be placed in the section of precautions for the workers is mandatory:

„*Stosować rękawice ochronne oraz odzież roboczą podczas wchodzenia na teren poddany zabiegowi*."

"Wear protective gloves and work wear during when entering the treated area.".

3.4.4 Bystander and resident exposure

The exposure of bystander and resident (children and adult) to the formulation MEZOFLOR 103 SC causes acceptable risk to human health if:

- warning boards preventing from resident/bystander entry into treated area are installed and remain till the end of cultivation,
- min. 5-meter buffer zone is kept during spraying
- drift-reduction nozzles are used.

Following sentence regarding the use of risk mitigation measures should be placed in the section of precautions for the bystander/resident:

Podczas wykonywania zabiegu należy zachować 5 metrową strefę buforową oraz dysze ograniczające znos. Należy umieścić tablicę informacyjną: „Zakaz wejścia na teren poddany opryskowi do końca uprawy".
Keep a 5 meter buffer zone and drift-reduction nozzles during application. Warning board should be placed: "*Do not enter the treated area till the end of the plant growth"*.

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

3.5.1 Residues

Mesotrione

Storage stability

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

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

Metabolism in plants and animals

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

Plant residue definition for monitoring Mesotrione (cereals and pulses/oilseeds only) - EFSA journal 2016;14(3):4419; Reg. (EU) 2017/626 and Reg. (EU) 2024/1077.

Plant residue definition for risk assessment:

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

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

Magnitude of residues in plants

Proposed GAP for maize (1 application, BBCH 12-18, 100 - 125 g as/ha) is within the EU GAP (SANTE/11654/2016, 23 March 2017).

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

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

Magnitude of residues in livestock

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

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 MEZOFLOR 103 SC do not represent unacceptable acute and chronic risks for the consumer. Calculations are accepted.

Florasulam

Stability of Residues

Storage stability of florasulam was demonstrated in cereal grain, cereal straw and immature cereal plants for a period of 18 to 23 month at temperature ranging from -18°C to -25°C.

Sufficient stability has been demonstrated to support the residue data presented in this document.

No further data are required to support the proposed uses.

Metabolism in plants and animals

The data evaluated during the Annex I inclusion and renewal process of the active substance are sufficient to describe the behaviour of the formulated product, and no further studies are required.

Plant and animal residue definitions for monitoring: Florasulam (Reg. (EU) 2022/1363)

Plant residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam and provisionally 4-OH- phenyl-florasulam (data gap)

Animal residue definition for risk assessment (EFSA Journal 2015;13(1): 3984): Florasulam pending assessment with regard to 4-OH-phenyl-florasulam

Conversion factor (monitoring to risk assessment): For milk, liver, kidney and eggs: 1

The data gap concerns the further toxicological evaluation of the plant metabolite 4-OH- phenyl-florasulam.

Magnitude of residues in plants

Proposed GAP (maize): 1 application, BBCH 12-18, 3.00 -3.75 g as/ha

Applicant refers to unprotected EU data.

Sufficient trials on cereals are available to support the proposed uses.

Residues from trials are all below 0.01 mg/kg.

The residues arising from the proposed uses will not exceed the MRLs established for cereals (0.01 mg/kg; Reg. (EU) 2022/1363)

Magnitude of residues in livestock

The new animal model calculation (Excel spreadsheet Animal model 2017) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be

exceeded. Supplementary livestock feeding studies are not required. Calculations provident by the applicant are accepted.

Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

As quantifiable residues of florasulam are not expected in edible part of crops based on available residue data, there is no need to investigate the effect of industrial and/or household processing.

Magnitude of residues in representative succeeding crops

Considering available data dealing with nature of residues, no study dealing with magnitude of residues in succeeding crops is needed.

EFSA Journal 2015; 13(1):*3984: In the section on residues data gaps were identified with regard to residues in animal commodities and rotational crops. Nonetheless, the margin of safety in the consumer risk assessment is considered big even if the potentially relevant toxicological burden for consumers via their diet might have been underestimated in the current assessment.*

Residues of parent florasulam in succeeding crops are not sufficient to reach measurable levels in monitoring (<0.01 mg/kg) and no specific plant-back restrictions related to florasulam are required.

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 Florasulam in the formulation MEZOFLOR 103 SC do not represent unacceptable chronic risks for the consumer.

Proposed use is accepted

3.5.2 Consumer exposure

The proposed uses of mesotrione and florasulam in the formulation MEZOFLOR 103 SC do not represent unacceptable acute and chronic risks for the consumer. The calculation for consumer risk assessment was made using EFSA PRIMo 3.1.

Consumer risk assessment - mesotrione

TMDI (% ADI) according to EFSA PRIMo	12 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	See TMDI value
IESTI (% ARfD) according to EFSA PRIMo*	Raw commodities 0.3% Maize/corn
	Processed commodities: 1% Maize/oil 0.1% Maize/processed
NTMDI (% ADI) **	Not assessed
NEDI (% ADI)**	Not assessed
NESTI (% ARfD) **	Not assessed

Consumer risk assessment – florasulam

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	2 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	See TMDI value
IESTI (% ARfD) according to EFSA PRIMo*	Not applicable
NTMDI (% ADI) **	Not assessed
NEDI (% ADI)**	Not assessed
NESTI (% ARfD) **	Not assessed

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

The predicted environmental concentrations (PEC values) in soil, surface water, sediment and groundwater are provided in Part B, Section 8. The long-term concentrations are based on results obtained for the active substance contained in the formulation. Calculated PEC values demonstrates that the MEZOFLOR 103 SC is safe for the environment.

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

The PEC_{soil} values were calculated for a single application in maize and for the highest application rate 1.25 L product/ha. Crop interception at this growth stage is 25% according „Generic Guidance for Tier 1 FOCUS Ground Water Assessments" (Version: 2.2; May 2014). Furthermore, the PEC_{soil} values assuming incorporation into a 5 cm soil layer with a density of 1.5 g/cm^3. For the calculations of active substance and its relevant metabolites, the worst-case (maximum) normalized laboratory DT_{50} values were used.

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

The Predicted Environmental Concentrations (PECgw) of mesotrione, forasulam and their metabolites were calculated with FOCUS PEARL (v 5.5.5.) and FOCUS PELMO (v. 6.6.4.) on the basis of EU agreed endpoints that were summarized at EU level. The PECgw were calculated for the highest application rate 1.25 l/ha recommended for use in maize (i.e. 125 g s.a. /ha of mesotrione and 3.75 g s.a./ha of florasulam). Nine scenarios were taken into consideration: Châteaudun, Hamburg, Okehampton, Kremsmünster, Jokioinen, Piacenza, Porto, Sevilla and Thiva.
Obtained PECgw for mesotrione, its metabolites, florasulam and its metabolites 5-OH florasulam and DFP-ASTCA in each scenario and for the recommended use of MEZOFLOR 103 SC are significant below the trigger value of 0.1 µg/L and therefore the use of this plant protection product according to recommendations does not pose a risk of groundwater contamination.
Obtained PECgw for florasulam's metabolites ASTCA and TSA were over the trigger value of 0.1 µg/L in 6 of 8 scenarios for DFP-ASTCA and in 4 of 8 scenarios for TSA.
Taking into account toxicological data, metabolites ASTCA and TSA are considered toxicologically non-relevant (EFSA Journal 2015;13(1): 3984). The PECgw values for both metabolites are below the upper limit for metabolites (<0.75 µg/l). Consequently, the consumer risk calculations for ASTCA and TSA are not required.

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

PEC_{SW} was calculated according to endpoints for mesotrione and florasulam and submitted for MEZOFLOR 103 SC.
The Predicted Environmental Concentrations in surface water has been calculated for active substances and their metabolites.
Since the low risk for aquatic organism were predicted due to calculations, no risk mitigations were considered.
Taking into consideration risk mitigation calculations for MEZOFLOR 103 SC use in maize, following risk mitigation measures should be applied:
- 4 m buffer non-spray zone with 4 meter vegetated filter strip.

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

The vapour pressure at 20 °C of the active substance mesotrione is $< 10^{-5}$ Pa. Hence the active substance mesotrione is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance mesotrione due to volatilization with subsequent deposition should be considered.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

Birds
An estimation of risk indicate low risk for birds for proposed uses in maize. Calculations conducted due to the influence formulation MEZOFLOR 103 SC due to the acute, long-term and reproductive toxicity did not indicate any hazardous properties and danger for birds. There was also no negative effects regarding to drinking water exposure and effect of secondary poisoning. There is no influence to evaluated organism regarding to dangerous to food poisoning.

There's no risk arising from bioaccumulation in food chains. There is no effect of secondary poisoning due to the consumption by birds feeding on fish or earthworms.

Mammals

In the screening step the TER_A values for mesotrione and florasulam exceeds the trigger value (10), indicating that MEZOFLOR 103 SC presents an acceptable acute risk to mammals.
The TER_{LT} values from the tier 1 reproductive risk assessment for florasulam are above the trigger of 5 for the use on maize, indicating that florasulam presents an acceptable long-term risk to mammals.
The TER_{LT} values from the tier 1 reproductive risk assessment for mesotrione are below the trigger of 5 for the use on maize, indicating that mesotrione presents an unacceptable long-term risk to mammals.
A higher tier long-term risk assessment based on the following refinement parameters: foliage residue dissipation (DT_{50}) and ecological data on PT values as well as ecological toxicity endpoints for mammals should be considered by MSs level.

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

zRMS agrees with the refined PT value (PT = 0.139) for wood mouse and PT value (PT = 0.62) for brown hare.

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

Refinement of DT_{50}

The f_{TWA} value used to refine the risk to mammals was calculated based on the residue level decrease study for the active substance mesotrione in corn (DT_{50}= 14h), authored by Schneider E. from 2016: "Determination of mesotrione and its metabolite (MNBA) residue In maize following treatment with Mesotrione 100 SC under field conditions in northern and southern France in 2015, together with the report by Hazlerigg C.: "A kinetic analysis of the dissipation of mesotrione in maize". The Applicant does not have the full report: "A kinetic analysis of the dissipation of mesotrione in maize". The risk calculation used unprotected data contained in the TEMSA SC product documentation (mesotrione, 100g/L), in which the report was described in detail. Authorization of the TEMSA SC product was renewed in Poland in accordance with the decision (MRiRW Permit No. R-190/2015 of 29.10.2015 renewed by MRiRW Decision No. R – 25 /2021o of 23.06.2021) of 23.06.2021. These studies were presented in connection with the need to refine the risk assessment for two mammalian species: *Apodemus sylvaticus* and *Lepus europaeus*, the data were necessary to obtain an acceptable risk assessment for the product TEMSA SC (mesotrione, 75-125 g/ha), in the process of renewal of the authorization in Poland.

The possibility of using these residue studies to refine risk assessments should be considered at Member State level.

Normally a DT_{50} of 10 days is assumed in the birds and mammals risk assessment as a default value. For this product **MEZOFLOR 103 SC** however, a lower DT_{50} could be expected based on five plant residue trials that were conducted in Europe (see dR Part B7 for a description of these studies). A kinetic analysis of the dissipation of mesotrione in maize was conducted by enviresearch and a report of this study was submitted to support this refinement of the DT_{50} of mesotrione on plants (Hazlerigg & Garratt, 2016).

FOCUS (2006, 2014) degradation kinetics guidance was applied to calculate DT_{50} endpoints for mesotrione modelling from residues measured in five plant residue trials in Europe. The data were described reasonably well by either SFO kinetics or bi-phasic FOMC kinetics and acceptable endpoints were derived for all five studies.

The calculated DT_{50} values and statistics for the decline of mesotrione in maize are shown in the table below. The DT_{50} values ranged from 10.1 to 21.9 hours. The final DT_{50} recommended for modelling is the geomean of 14 hours. The DT_{50} = 14 hours as geometric mean was also 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} = 21.9 hours and this value should be used in risk assessment. Estimated new f_{TWA} = 0.063 based on residue decline study will be used as a risk refinement for reproductive risk to mammals in post-emergence use. MAFm * TWA (refined DT_{50}) = 0.063 should be used in risk assessment. The registration dossier included 5 studies on the dynamics of residue depletion in maize (4 in the N-EU zone and 1 in the S-EU zone), on the basis of which the DT_{50} value was determined. In the opinion of RMS, one study of the southern zone residues (B5116 EF1) undermines the validity of using the geometric mean and should be excluded from the analysis. It is most reasonable to use the maximum value can be used DT_{50}.

Trial	Site	European area	Crop, variety	Trial type
B5116 AN1	Seebach, Alsace, France	North	Maize, Karedas	Decline curve
B5116 MA1	Donnelay, Lorraine, France	North	Maize, P3184	Decline curve
B5116 BM1	Thorée les Pins, Pays de la Loire, France	North	Maize, P9074	Decline curve
B5116 ND1	Hérin, Nord Pas de Calais, France	North	Maize, Ramses	Decline curve
B5116 EF1	Saint-Livrade, Aquitaine, France	South	Maize, Roberi	Decline curve

Table: Summary of fitted parameters for the decline of mesotrione.

Study	Kinetic model	t-test	$\chi 2$-error	Visual fit	DT50 (hours)
B5116 AN1	FOMC	n/a	7.93	Good	13.3 *
B5116 MA1	SFO	Pass	6.92	Good	21.9
B5116 BM1	SFO	Pass	14.3	Medium	10.1
B5116 ND1	FOMC	n/a	6.74	Good	15.2 *
B5116 EF1	FOMC	n/a	10.9	Good	12.1 *
Geomean of all trials					**14.0**

* Pseudo first-order DT_{50} calculated as FOMC $DT_{90}/3.32$ (FOCUS 2006, 2014)

Estimated new f_{TWA} = 0.063 based on residue decline study will be used as a risk refinement for reproductive risk to mammals in post-emergence use. The worst case is DT_{50} = 21.9 hours. Refinement of DT_{50} should be considered at MSs level.

Based on EFSA Conclusion 2016 voles are not representative species in maize. The focal species for maize at early BBCH growth stages such as wood mouse and brown hare were accepted by zRMS.

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

Maize 1 x 125 g a.s./ha

The refinement risk assessment for mammals was corrected by zRMS.

Intended use	Maize
Active substance/product	Mesotrione
Application rate (g a.s./ha)	1 × 125
Reprod. toxicity (mg/kg bw/d)	0.3
TER criterion	5

Crop scenario Growth stage	Indicator/generic focal species	SV_m	PT	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Maize BBCH 10-29	Brown hare *Lepus europaeus* (100% grass)	17.3[1)]	0.62	1 x 0.063	0.084	**3.57**

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

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

Intended use	Maize					
Active substance/product	Mesotrione					
Application rate (g a.s./ha)	1 × 125					
Reprod. toxicity (mg/kg bw/d)	0.3					
TER criterion	5					
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**PT**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize BBCH 10-29	*Apodemus sylvaticus*	7.8[1)]	0.139	1 x 0.063	0.0085	35.29

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

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

Based on the new f_{TWA} and refinement PT value application for brown hare is still unacceptable, therefore refinement of reproductive risk assessment for the herbivorous brown hare (*Lepus europaeus*) and the small omnivorous for Rabitt exposed to mesotrione is required as TER_{LT} is below the trigger of 5 (TER_{lt} = 3.57).

Maize 1 x 100 g a.s./ha

The refinement risk assessment for mammals was corrected by zRMS.

Intended use	Maize					
Active substance/product	Mesotrione					
Application rate (g a.s./ha)	1 × 100					
Reprod. toxicity (mg/kg bw/d)	0.3					
TER criterion	5					
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**PT**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize BBCH 10-29	Brown hare *Lepus europaeus* (100% grass)	17.3[1)]	0.62	1 x 0.063	0.068	**4.41**

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

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

Intended use	Maize					
Active substance/product	Mesotrione					
Application rate (g a.s./ha)	1 × 100					
Reprod. toxicity (mg/kg bw/d)	0.3					
TER criterion	5					
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**PT**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize BBCH 10-29	*Apodemus sylvaticus*	7.8[1)]	0.139	1 x 0.063	0.0068	44.12

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

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

Based on the new f_{TWA} and refinement PT value application for brown hare is still unacceptable, therefore refinement of reproductive risk assessment for the herbivorous brown hare (*Lepus europaeus*) and the small omnivorous for Rabitt exposed to mesotrione is required as TER_{LT} is below the trigger of 5 (TER_{lt} = 4.41).

Based on the new f_{TWA} and refinement PT value - application for brown hare is still unacceptable, therefore refinement of reproductive risk assessment for the herbivorous brown hare (*Lepus europaeus*) and the small omnivorous for Rabitt exposed to Mesotrione based on refined NOEAL of 1.2 mg a.s./kg bw.
Justification: The information available in the mesotrione RAR of 2015 (Vol. 3CA, B.6) indicates that in fact, slightly reduced pup survival at 10 ppm (1.2 mg a.s./kg bw/d) was incidental and not treatment related, as at the next higher dose (100 ppm) the pup survival was at the level comparable with control values. For this reason it seems that for purposes of the ecological risk assessment NOAEL of 1.2 mg a.s./kg bw/d could be considered relevant and was actually proposed by the RMS (UK).

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

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

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

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

Higher-tier assessment of the long term risk for mammals due to the mesotrione use of MEZOFLOR 103 SC in maize

\Intended use		maize						
Active substance/product		mesotrione						
Application rate (g/ha)		1 × 125						
Reprod. toxicity (mg/kg bw/d)		1.2						
TER criterion		5						
Crop scenario Growth stage	**Indicator/generic focal species**	**Fir/bw**	**RUD**	**SV_m**	**MAF_m × TWA***	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize	Rabbit (100 % plant material)	0.334	54.2	-	0.063	0.62	0.088	13.63

* **The worst case is DT_{50} = 21.9 hours**

Higher-tier assessment of the long term risk for mammals due to the mesotrione use of MEZOFLOR 103 SC in maize

\Intended use		maize
Active substance/product		mesotrione
Application rate (g/ha)		1 × 100
Reprod. toxicity (mg/kg bw/d)		1.2
TER criterion		5

Crop scenario Growth stage	**Indicator/generic focal species**	**Fir/bw**	**RUD**	**SV_m**	**MAF_m × TWA***	**PT**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Maize	Rabbit (100 % plant material)	0.334	54.2	-	0.063	0.62	0.07	17

* **The worst case is DT_{50} = 21.9 hours**

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.

Based on the risk refinement based on refinement toxicity endpoints, F_{twa} value and PT value it can be concluded that application of **MEZOFLOR 103 SC** according to the label will not pose no unacceptable reproductive risk to mammals.

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

3.7.2 Effects on aquatic species

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

Taking into consideration risk mitigation calculations for MEZOFLOR 103 SC – use in Orchards, following risk mitigation measures should be applied:
- 4 m buffer non-spray zone with 4 meter vegetated filter strip.

3.7.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). The risk assessment for bees and bumblebee was carried out regarding oral and dermal toxicity endpoints and individual application rates.
The Q_{HO}, Q_{HC} values for MEZOFLOR 103 SC are below the trigger value recommended by the EFSA

Journal 2012; 10(5):2668, and therefore the risk for bees is regarded as acceptable.

3.7.4 Effects on other arthropod species other than bees

A. rhopalosiphi and *T. pyri* are organisms used to designation the initial assessment.
$HQ_{in\text{-}field}$ and $HQ_{off\text{-}field}$ values for *A. rhopalosiphi* and *T. pyri* are below the ESCORT 2 trigger of 2. The calculations present an acceptable risk to non-target arthropods, after spray application of MEZOFLOR 103 SC.

3.7.5 Effects on soil organisms

The calculated chronic TER for active substances, their metabolites and formulation are above the trigger value of 5 indicating acceptable chronic risk to earthworms from the proposed uses of MEZOFLOR 103 SC. On the basis of results it was assessed that MEZOFLOR103 SC in considered applications does not pose unacceptable risk to soil microorganisms. The risk to soil micro-organisms is considered to be low for all representative uses.

The studies for formulation of MEZOFLOR 103 SC for earthworms and *Folsomia candida* and *Hypoaspis aculeifer* with risk assessment was accepted by zRMS only provisionally. The toxicity endpoints were based on nominal concentration. At the end on the studies concentration of substances active fell under 80% of nominal. The TWA or geometric mean measured concentration should be calculated over the duration of the test and used if the concentration falls under 80% of nominal. The Applicant should complete the calculation the toxicity endpoints based on geometric mean measured concentration with risk assessment.

In the opinion of the Applicant, when dealing with non-persistent substances, it is not possible to determine the geometric mean of all 3 measurement points and underestimate the endpoints, because this would be tantamount to the fact that the decomposition of the active substance in its normal time in the soil, generates more toxicity caused by these substances and not by its metabolites, which seems to make no physical sense.

Therefore, the Applicant has used endpoints based on the nominal value of the active substances in the calculation. In the dRR submitted for evaluation, the applicant submitted a risk assessment based on a nominal value which is the worst case calculation.

In the opinion of the applicant, the optional determination of new endpoints should be based on the use of the recovery factor, determined in the amendments to the test reports, according to the assumption that the loss of active substances in the soil, due to their decomposition after 56, 28 or 14 days, causes a reduction in the toxicity of the formulation resulting from the action of these substances, and consequently an increase in the value of the endpoints (see section B9). The presented endpoints are not the worst case, that's why the risk assessment for the soil organisms are not recalculated for this endpoints.

zRMS comment:

The new data with toxicity endpoints recalculation and justification that in this case the best solution is to use endpoints based on nominal concentration in risk assessment for soil organisms was provided by Ap-

plicant. The recalculation should be treated as additional source information. **In this case, when the concentration values fall below the limit of quantification of the analytical method, it is not possible to determine reliable toxicity endpoints based on geometrically measured concentrations.** In addition, it can be noted that a decrease in the content of the active substance in the experimental system, caused by the decomposition of this substance (documented low DT_{50}, DT_{90} in soil, confirmed by analytical tests) usually causes a decrease in the toxicity caused by this substance. In the case of unstable substances, precise specification of reliable endpoints based on the measured geometric mean is not possible, especially when the concentration values fall below the limit of quantification of the analytical method. In order to reliably measure the decrease in such rapidly dispersing compounds, more time points of sampling at much shorter intervals (even within the first day) and a much higher number of repetitions may be necessary. Detailed technical guidance on the design of ecotoxicological studies is needed before analytical measurements are routinely included in ecotoxicological studies involving soil invertebrates. Therefore, the revision and validation of the technical guidelines (OECD 222, 232, 226; 2016 a, b, c) is necessary to achieve greater clarity. The study of soil organisms in ecotoxicology differs significantly from, for example, routine aquatic testing procedures, therefore the implementation of such appropriate analysis in the relevant tests cannot be easily adapted or transferred. The risk assessment for soil organisms, in this case, based on toxicity endpoints based on nominal concentration was accepted by zRMS.

3.7.6 Effects on non-target terrestrial plants

Taking into consideration risk mitigation calculations for MEZOFLOR 103 SC – use in maize, following risk mitigation measures should be applied:

- **5 m buffer zone and 75 % drift reduction nozzle,**
- **10 m buffer zone and 50 % drift reduction nozzle,**
- **15 m buffer zone.**

Using the above-mentioned precautions, formulation MEZOFLOR 103 SC can be used and will not have a negative impact on non-target terrestrial plants.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.8 Relevance of metabolites (Part B, Section 10)

The relevance of the groundwater metabolite ASTCA and TSA has already been assessed and the assessment agreed at EU level (EFSA Journal 2015; 13(1):3984) and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{gw} calculated for the GAP and groundwater scenarios considered in this dRR).

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

Not relevant.
MEZOFLOR 103 SC do not contain active substances approved as a 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

Fizyko-chemia: Do zapisów w etykietach środków MEZOFLOR 103 SC i FLOCORN 103 SC należy dodać następujący zwrot: "Przed użyciem środek dokładnie wymieszać."

Metabolizm i pozostałości: brak uwag

Skuteczność: Wprowadzono zmiany do listy zaakceptowanych gatunków chwastów. Dodano zapis: kukurydza *uprawiana na ziarno, kiszonkę i bioetanol* oraz "*Wyższa z dawek powinna być stosowana w warunkach większego zachwaszczenia pola lub w przypadku wyższej fazy rozwojowej chwastów*". Pozostałych zapisów – nie zmieniano.

Ekotoksykologia: Zaakceptowano.

Posiadacz zezwolenia:
Synthos Agro Sp. z o. o., ul. Chemików 1, 32 – 600 Oświęcim, tel. + 48 (33) 847 47 77,
e – mail: rejestracja@synthosgroup.com

MEZOFLOR 103 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:
mezotrion (związek z grupy trójketonów) – **100 g/l (9,42%).**
florasulam (związek z grupy triazolopirymidyn) - **3 g/l (0,28%).**

Zezwolenie MRiRW nr ……. z dnia……,


Uwaga	
H361d	Podejrzewa się, że działa szkodliwie na płodność lub dziecko w łonie matki.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
EUH 208	Zawiera 1,2-benzizotiazol3(2H)-on. Może powodować wystąpienie reakcji aler-

	gicznej.
P202	Nie używać przed zapoznaniem się i zrozumieniem wszystkich środków bezpieczeństwa.
P273	Unikać uwolnienia do środowiska.
P280	Stosować rękawice ochronne oraz odzież ochronną, ~~ochronę oczu, ochronę twarzy~~.
P308 + P313	W przypadku narażenia lub styczności: skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem.
P391	Zebrać wyciek.
P501	Zawartość, pojemnik usuwać do firm posiadających odpowiednie uprawnienia.

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany nalistnie w postaci koncentratu w formie stężonej zawiesiny do rozcieńczania wodą, przeznaczony do zwalczania chwastów jednoliściennych i dwuliściennych w uprawie kukurydzy. Środek przeznaczony jest do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.
Zgodnie z klasyfikacją HRAC substancja czynna mezotrion zaliczana jest do grupy 27.
Zgodnie z klasyfikacją HRAC substancja czynna florasulam zaliczana jest do grupy 2.

DZIAŁANIE NA CHWASTY

Środek zawiera dwie substancje czynne o odmiennym mechanizmie działania. Mezotrion jest zaliczany do inhibitorów biosyntezy karotenoidów, w następstwie czego powoduje zniszczenie chlorofilu, co skutkuje bieleniem się liści. Pobierany jest przez liście chwastów oraz dodatkowo przez korzenie, szybko przemieszcza się w roślinie, co prowadzi do ograniczenia jej wzrostu i rozwoju. Florasulam blokuje działanie enzymu syntetazy acetylomleczanowej (ALS), który bierze udział w biosyntezie aminokwasów, co powoduje w konsekwencji zahamowania wzrostu i rozwoju chwastów. Pobierany jest przez liście chwastów, a następnie przemieszczany w roślinie.

Dawka 1,0 l/ha

Chwasty wrażliwe:	Tasznik pospolity, żółtlica drobnokwiatowa, tobołki polne, rumianek pospolity, rumian polny
Chwasty średnio wrażliwe:	Komosa biała, przytulia czepna, ~~psianka czarna,~~ maruna bezwonna (nadmorska), fiołek polny, chaber bławatek, gwiazdnica pospolita, bodziszek drobny, rdestówka powojowata (rdest powojowaty), samosiewy rzepaku, ~~szarlat szorstki, farbownik polny~~
Chwasty odporne	chwastnica jednostronna

Dawka 1,25 l/ha

Chwasty wrażliwe:	Komosa biała, przytula czepna, ~~psianka czarna,~~ tasznik pospolity, żółtlica drobnokwiatowa, tobołki polne, rumianek pospolity, maruna bezwonna (nadmorska), rumian polny, fiołek polny, gwiazdnica pospolita, rdestówka powojowata (rdest powojowaty), ~~rdest plamisty, szarlat szorstki, farbownik polny~~
Chwasty średniowrażliwe:	Chaber bławatek, bodziszek drobny, samosiewy rzepaku, chwastnica jednostronna

STOSOWANIE ŚRODKA

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

Kukurydza uprawiana na kiszonkę, ziarno i bioetanol

Maksymalna dawka dla jednorazowego zastosowania: 1,25 l/ha.
Zalecana dawka dla jednorazowego zastosowania: 1,0-1,25 l/ha.
Termin stosowania: Środek stosować od fazy 2 liści do fazy 8 liści kukurydzy (BBCH 12-18).
Wyższa z dawek powinna być stosowana w arunkach większego zachwaszczenia pola lub w przypadku wyższej fazy rozwojowej chwastów.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 – 300 l/ha
Zalecane opryskiwanie: średniokropliste.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

1. W przypadku suszy po kilku do kilkunastu dniach po zabiegu liście niektórych odmian mogą się odbarwić (białe wydłużone plamy). Objawy te są przemijające, nie mają wpływu na dalszy rozwój i plonowanie. Należy unikać stanowisk wcześniej odchwaszczanych (w danym sezonie) amidosulfuronem. Tej substancji czynnej nie zaleca się bezpośrednio po zastosowaniu produktu. Ujemnie wpływają przymrozki występujące przed zabiegiem jak i po nim.
2. 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.
3. Nie zaleca się stosowania środka MEZOFLOR 103 SC w uprawie linii wsobnych kukurydzy oraz na plantacjach nasiennych, bez uprzedniego sprawdzenia wrażliwości na środek, a także w kukurydzy cukrowej.
4. Podczas stosowania środka nie dopuścić do:
– znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
– nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
5. Strategia zarządzania odpornością.

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów, herbicydy powinny być stosowane zgodnie z Dobrą Praktyką Rolniczą:

– postępuj zgodnie z zaleceniami zawartymi w etykiecie środka ochrony roślin – stosuj środek w zalecanej dawce w terminie zapewniającym najlepsze zwalczanie chwastów,
– dostosuj zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
– używaj różnych metod regulowania zachwaszczenia w tym rotację upraw, itp.,
– stosuj rotacje herbicydów o różnym (odmiennym) mechanizmie działania,
– stosuj mieszanki herbicydów o odmiennym mechanizmie działania,
– stosuj w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów,
– stosuj herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
– informuj posiadacza zezwolenia o niesatysfakcjonującym zwalczaniu chwastów,

- w celu uzyskania szczegółowych informacji skontaktuj się z doradcą, posiadaczem zezwolenia dla środka lub przedstawicielem posiadacza.
- Środka nie należy stosować na stanowiskach gdzie występują biotypy chwastów o potwierdzonej odporności na substancje czynne zaliczane zgodnie z klasyfikacją HRAC do grupy 2 oraz 27. Ostrożność należy zachować również przy stosowaniu środków zawierających substancje czynne zaliczane zgodnie z klasyfikacją HRAC do grupy 1, 3 oraz 9.

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

NASTĘPSTWO ROŚLIN

W skrajnie niekorzystnych warunkach (gleby piaszczyste, gleby łatwo przesychające, gleby o niskim pH [<6.0], gleby o wysokiej zawartości substancji organicznej [>4.0%], niskiej aktywności biologicznej, wyjątkowo niskich temperaturach w okresie zimowym, wyjątkowo niskiej wilgotności gleby latem i/lub jesienią i/lub zimą, nakładania się powierzchni opryskanej preparatem, gleby nadmiernie ugniecionej) mogą wystąpić tymczasowe wybielenia, zahamowanie wzrostu, zmniejszenie obsady w roślinach wrażliwych (buraki, strączkowe, słonecznik i warzywa). Dlatego też uprawa w/w roślin jako roślin następczych nie jest zalecana, gdy pH gleby jest znacznie poniżej 6.0 lub jeśli po zastosowaniu środka w poprzednim sezonie, wystąpił długotrwały okres posuchy. Orka na głębokość min. 15 cm po uprawie kukurydzy i pH gleby ponad 6.0 znacząco zmniejszają ryzyko uszkodzeń tych roślin.
W przypadku konieczności wcześniejszego zaorania plantacji traktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki) na tym samym polu po wykonaniu uprawy przedsiewnej można uprawiać tylko kukurydzę lub życice trwałą. Po wykonaniu orki na głębokość min. 15 cm oprócz w/w roślin można także uprawiać sorgo.
Natomiast rzepak ozimy może być wysiany dopiero jesienią następnego roku, podobnie w przypadku buraka cukrowego (wiosną następnego roku od ostatniego zastosowania środka).
Po zbiorze kukurydzy uprawianej na ziarno i kiszonkę w normalnych warunkach wegetacji można uprawiać:
– na jesieni - zboża ozime oraz rzepak ozimy i warzywa kapustne. Przed siewem rzepaku ozimego i warzyw kapustnych koniecznym jest wykonanie orki na głębokość min. 15 cm.
– na wiosnę - kukurydzę (uprawianą na ziarno i kiszonkę) oraz pszenicę jarą i jęczmień jary.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.
Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed użyciem środek dokładnie wymieszać. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Następnie zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości.
Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać.
W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy, dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

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

- 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.

Bezpośrednio po zabiegu aparaturę dokładnie wymyć.
Z wodą użytą do mycia aparatury postępować tak jak z resztkami cieczy użytkowej.
W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować stosowanie do instrukcji dołączonej do środka myjącego.

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 roboczej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.
Unikać zanieczyszczenia oczu.
Operator: Stosować rękawice ochronne, odzież ochronną odpowiednie obuwie w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.
Pracownik polowy: Stosować rękawice ochronne oraz odzież roboczą podczas wchodzenia na teren poddany zabiegowi.
Osoby postronne: W czasie oprysku należy zastosować:
co najmniej 5 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych,
techniki zmniejszające znoszenie preparatu (dysze antyznoszeniowe, mała prędkość pojazdu, stabilna pogoda i inne).
Po wykonaniu zabiegu umieść w widocznych miejscach wokół pola tablice ostrzegawcze z napisem „Zakaz wstępu osób niepowołanych do obszaru poddanego działaniu środków ochrony roślin".

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

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.
Nie myć aparatury w pobliżu wód powierzchniowych.
Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.
W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 4 m od zbiorników i cieków wodnych lub

W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości:

- 5 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%, lub
- 10 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub

– 15 m.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:

- pod zamknięciem,
- 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 0ºC-30ºC.

Chronić przed nasłonecznieniem i wilgocią.
Przechowywać pojemnik szczelnie zamknięty.
Przechowywać z dala od źródeł ciepła.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.
Używać odpowiednich pojemników zapobiegających skażeniu środowiska.
Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

PIERWSZA POMOC
Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.
W przypadku narażenia lub styczności: skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem
~~W przypadku dostania się do oczu ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.~~
~~W przypadku utrzymania się działania drażniącego na oczy: zgłosić się pod opiekę lekarza.~~

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

Fizyko-chemia: Do zapisów w etykietach środków MEZOFLOR 103 SC i FLOCORN 103 SC należy dodać następujący zwrot: “Przed użyciem środek dokładnie wymieszać.”

Metabolizm i pozostałości: brak uwag

Skuteczność: Wprowadzono zmiany do listy zaakceptowanych gatunków chwastów. Dodano zapis: kukurydza *uprawiana na ziarno, kiszonkę i bioetanol* oraz "*Wyższa z dawek powinna być stosowana w warunkach większego zachwaszczenia pola lub w przypadku wyższej fazy rozwojowej chwastów*". Pozostałych zapisów – nie zmieniano.

Ekotoksykologia: Ocena ryzyka oraz badania środka **MEZOFLOR 103 SC** na dżdżownice i inne makroorganizmy glebowe (*Folsomia candida* i *Hypoaspis aculeifer*) zostały zaakceptowane przez zRMS tymczasowo. Wymagane przeliczenie końcowych punktów toksyczności w oparciu o średnią geometryczną mierzonego stężenia.

Posiadacz zezwolenia:
Synthos Agro Sp. z o. o., ul. Chemików 1, 32 – 600 Oświęcim, tel. + 48 (33) 847 47 77,
e – mail: rejestracja@synthosgroup.com

FLOCORN 103 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:
mezotrion (związek z grupy trójketonów) – **100 g/l (9,42%).**
florasulam (związek z grupy triazolopirymidyn) - **3 g/l (0,28%).**

Zezwolenie MRiRW nr ……. z dnia…….,

Uwaga	
H361d	Podejrzewa się, że działa szkodliwie na płodność lub dziecko w łonie matki.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
EUH 208	Zawiera 1,2-benzizotiazol3(2H)-on. Może powodować wystąpienie reakcji alergicznej.
P202	Nie używać przed zapoznaniem się i zrozumieniem wszystkich środków bezpieczeństwa.

P273	Unikać uwolnienia do środowiska.
P280	Stosować rękawice ochronne oraz odzież ochronną, ~~ochronę oczu, ochronę twarzy~~.
P308 + P313	W przypadku narażenia lub styczności: skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem.
P391	Zebrać wyciek.
~~P501~~	~~Zawartość, pojemnik usuwać do firm posiadających odpowiednie uprawnienia.~~

OPIS DZIAŁANIA

HERBICYD selektywny o działaniu układowym, stosowany nalistnie w postaci koncentratu w formie stężonej zawiesiny do rozcieńczania wodą, przeznaczony do zwalczania chwastów jednoliściennych i dwuliściennych w uprawie kukurydzy. Środek przeznaczony jest do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.
Zgodnie z klasyfikacją HRAC substancja czynna mezotrion zaliczana jest do grupy 27.
Zgodnie z klasyfikacją HRAC substancja czynna florasulam zaliczana jest do grupy 2.

DZIAŁANIE NA CHWASTY

Środek zawiera dwie substancje czynne o odmiennym mechanizmie działania. Mezotrion jest zaliczany do inhibitorów biosyntezy karotenoidów, w następstwie czego powoduje zniszczenie chlorofilu, co skutkuje bieleniem się liści. Pobierany jest przez liście chwastów oraz dodatkowo przez korzenie, szybko przemieszcza się w roślinie, co prowadzi do ograniczenia jej wzrostu i rozwoju. Florasulam blokuje działanie enzymu syntetazy acetylomleczanowej (ALS), który bierze udział w biosyntezie aminokwasów, co powoduje w konsekwencji zahamowania wzrostu i rozwoju chwastów. Pobierany jest przez liście chwastów, a następnie przemieszczany w roślinie.

Dawka 1,0 l/ha

Chwasty wrażliwe:	Tasznik pospolity, żółtlica drobnokwiatowa, tobołki polne, rumianek pospolity, rumian polny
Chwasty średnio wrażliwe:	Komosa biała, przytulia czepna, ~~psianka czarna,~~ maruna bezwonna (nadmorska), fiołek polny, chaber bławatek, gwiazdnica pospolita, bodziszek drobny, rdestówka powojowata (rdest powojowaty), samosiewy rzepaku, ~~szarlat szorstki, farbownik polny~~
Chwasty odporne	chwastnica jednostronna

Dawka 1,25 l/ha

Chwasty wrażliwe:	Komosa biała, przytula czepna, ~~psianka czarna,~~ tasznik pospolity, żółtlica drobnokwiatowa, tobołki polne, rumianek pospolity, maruna bezwonna (nadmorska), rumian polny, fiołek polny, gwiazdnica pospolita, rdestówka powojowata (rdest powojowaty), ~~rdest plamisty, szarlat szorstki, farbownik polny~~
Chwasty średniowrażliwe:	Chaber bławatek, bodziszek drobny, samosiewy rzepaku, chwastnica jednostronna

STOSOWANIE ŚRODKA

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

Kukurydza uprawiana na kiszonkę, ziarno i bioetanol

Maksymalna dawka dla jednorazowego zastosowania: 1,25 l/ha.
Zalecana dawka dla jednorazowego zastosowania: 1,0-1,25 l/ha.
Termin stosowania: Środek stosować od fazy 2 liści do fazy 8 liści kukurydzy (BBCH 12-18).
Wyższa z dawek powinna być stosowana w arunkach większego zachwaszczenia pola lub w przypadku wyższej fazy rozwojowej chwastów.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1.

Zalecana ilość wody: 200 – 300 l/ha
Zalecane opryskiwanie: średniokropliste.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

1. W przypadku suszy po kilku do kilkunastu dniach po zabiegu liście niektórych odmian mogą się odbarwić (białe wydłużone plamy). Objawy te są przemijające, nie mają wpływu na dalszy rozwój i plonowanie. Należy unikać stanowisk wcześniej odchwaszczanych (w danym sezonie) amidosulfuronem. Tej substancji czynnej nie zaleca się bezpośrednio po zastosowaniu produktu. Ujemnie wpływają przymrozki występujące przed zabiegiem jak i po nim.
2. 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.
3. Nie zaleca się stosowania środka MEZOFLOR 103 SC w uprawie linii wsobnych kukurydzy oraz na plantacjach nasiennych, bez uprzedniego sprawdzenia wrażliwości na środek, a także w kukurydzy cukrowej.
4. Podczas stosowania środka nie dopuścić do:
   – znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
   – nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
5. Strategia zarządzania odpornością.

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów, herbicydy powinny być stosowane zgodnie z Dobrą Praktyką Rolniczą:

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

6. Środka nie należy stosować na stanowiskach gdzie występują biotypy chwastów o potwierdzonej odporności na substancje czynne zaliczane zgodnie z klasyfikacją HRAC do grupy 2 oraz 27.

Ostrożność należy zachować również przy stosowaniu środków zawierających substancje czynne zaliczane zgodnie z klasyfikacją HRAC do grupy 1, 3 oraz 9.

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

NASTĘPSTWO ROŚLIN

W skrajnie niekorzystnych warunkach (gleby piaszczyste, gleby łatwo przesychające, gleby o niskim pH [<6.0], gleby o wysokiej zawartości substancji organicznej [>4.0%], niskiej aktywności biologicznej, wyjątkowo niskich temperaturach w okresie zimowym, wyjątkowo niskiej wilgotności gleby latem i/lub jesienią i/lub zimą, nakładania się powierzchni opryskanej preparatem, gleby nadmiernie ugniecionej) mogą wystąpić tymczasowe wybielenia, zahamowanie wzrostu, zmniejszenie obsady w roślinach wrażliwych (buraki, strączkowe, słonecznik i warzywa). Dlatego też uprawa w/w roślin jako roślin następczych nie jest zalecana, gdy pH gleby jest znacznie poniżej 6.0 lub jeśli po zastosowaniu środka w poprzednim sezonie, wystąpił długotrwały okres posuchy. Orka na głębokość min. 15 cm po uprawie kukurydzy i pH gleby ponad 6.0 znacząco zmniejszają ryzyko uszkodzeń tych roślin.
W przypadku konieczności wcześniejszego zaorania plantacji traktowanej środkiem (w wyniku uszkodzenia roślin przez przymrozki, choroby lub szkodniki) na tym samym polu po wykonaniu uprawy przedsiewnej można uprawiać tylko kukurydzę lub życice trwałą. Po wykonaniu orki na głębokość min. 15 cm oprócz w/w roślin można także uprawiać sorgo.
Natomiast rzepak ozimy może być wysiany dopiero jesienią następnego roku, podobnie w przypadku buraka cukrowego (wiosną następnego roku od ostatniego zastosowania środka).
Po zbiorze kukurydzy uprawianej na ziarno i kiszonkę w normalnych warunkach wegetacji można uprawiać:
– na jesieni - zboża ozime oraz rzepak ozimy i warzywa kapustne. Przed siewem rzepaku ozimego i warzyw kapustnych koniecznym jest wykonanie orki na głębokość min. 15 cm.
– na wiosnę - kukurydzę (uprawianą na ziarno i kiszonkę) oraz pszenicę jarą i jęczmień jary.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.
Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.
Przed użyciem środek dokładnie wymieszać. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Następnie zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości.
Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać.
W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy, dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

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

- 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.

Bezpośrednio po zabiegu aparaturę dokładnie wymyć.
Z wodą użytą do mycia aparatury postępować tak jak z resztkami cieczy użytkowej.
W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować stosowanie do instrukcji dołączonej do środka myjącego.

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 roboczej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.
Unikać zanieczyszczenia oczu.
Operator: Stosować rękawice ochronne, odzież ochronną odpowiednie obuwie w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.
Pracownik polowy: Stosować rękawice ochronne oraz odzież roboczą podczas wchodzenia na teren poddany zabiegowi.
Osoby postronne: W czasie oprysku należy zastosować:
co najmniej 5 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych,
techniki zmniejszające znoszenie preparatu (dysze antyznoszeniowe, mała prędkość pojazdu, stabilna pogoda i inne).
Po wykonaniu zabiegu umieść w widocznych miejscach wokół pola tablice ostrzegawcze z napisem „Zakaz wstępu osób niepowołanych do obszaru poddanego działaniu środków ochrony roślin".

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

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.
Nie myć aparatury w pobliżu wód powierzchniowych.
Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości:

- 4 m od zbiorników i cieków wodnych lub

W celu ochrony roślin niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości:

- 5 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%, lub
- 10 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%, lub

- 15 m.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:

- pod zamknięciem,
- 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 0ºC-30ºC.

Chronić przed nasłonecznieniem i wilgocią.
Przechowywać pojemnik szczelnie zamknięty.
Przechowywać z dala od źródeł ciepła.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.
Używać odpowiednich pojemników zapobiegających skażeniu środowiska.
Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

PIERWSZA POMOC
Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.
W przypadku narażenia lub styczności: skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem
~~W przypadku dostania się do oczu ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.~~
~~W przypadku utrzymania się działania drażniącego na oczy: zgłosić się pod opiekę lekarza.~~

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

Appendix 3 Letter of Access

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.2.1	Daniel Buczkow-ski	2021	MEZOFLOR 103 SC Determination of explosive properties Study code number: BW – 14/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.2.2	Paulina Flasińska	2021	MEZOFLOR 103 SC Determination of flash point, auto – ignition temperature and oxidising properties Study code number: BC – 21/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.3.1	Paulina Flasińska	2022	MEZOFLOR 103 SC Determination of flash point, Study code number: BC – 04/22	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
			Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished				
KCP 2.3.3	Paulina Flasińska	2021	MEZOFLOR 103 SC Determination of flash point, auto – ignition temperature and oxidising properties Study code number: BC – 21/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.4.1	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.4.2	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.5.1	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
			Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished				
KCP 2.5.2	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.6.1	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.7.1	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.7.3	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
			initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished				o.o
KCP 2.7.4	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.7.5	Jarosław Kupiec	2022	MEZOFLOR 103 SC Part II: Determination of physicochemical properties of the preparation after one year of storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2022 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.7.5	Jarosław Kupiec	2023	MEZOFLOR 103 SC Determination of physochemical properties. Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2023 GLP Unpublished	N	Y	Data never submitted in Poland	Synthos Agro Sp. z o.o.
KCP 2.8.2	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
			storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished				
KCP 2.8.3	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.8.5	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.8.7	Enzo Arévalo	2021	MEZOFLOR 103 SC Part I: Determination of physicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 2.11	Renata Buczek,	2021	MEZOFLOR 103 SC	N	Y	Study report never submitted in	Synthos

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
	Piotr Paleń		Effectiveness of the equipment cleaning procedure Study code number: AGRO/1/21 Synthos Agro Sp.z o.o. Oświęcim, 2021 Non – GLP Unpublished			Poland	Agro Sp. z o.o
KCP 5.1.1	Enzo Arévalo	2021	MEZOFLOR 103 SC Determination of phsicochemical properties of the initial preparation, after accelerated and low temperature storage Study code number: BF – 20/21 Łukasiewicz – Institute of Industrial Organic Chemistry Warsaw, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 5.1.2	Małgorzata Czarnecka	2021	Daphnia magna, Acute immobilisation Test Study code number: W-56-20 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Pszczyna, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 5.1.2	Elżbieta Kulec-Płoszczyca	2021a	Honeybees, (Apis mellifera L.) Chronic Oral Toxicity Test Study code number B-16-21 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Pszczyna, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 5.1.2	Elżbieta Kulec-Płoszczyca	2021b	Bumblebees, (Bombus spp.) Acute Oral Toxicity Test Study code number B-19-21 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Pszczyna, 2021 GLP	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 5.1.2	Elżbieta Kulec-Płoszczyca	2021c	Bumblebees, (Bombus spp.) Acute Contact Toxicity Test Study code number B-20-21 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Pszczyna, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 5.1.2	Ewa Nierzędska	2021	Raphidocelis subcapitata SAG 61.81 (formerly Pseudo-kirchneriella subcapitata), Growth inhibition test Study code number B-57-20 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Pszczyna, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 5.1.2	Paweł Pieczka	2021a	Earthworm reproduction test (Eisenia andrei) Study code number G-63-20 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Pszczyna, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 5.1.2	Paweł Pieczka	2021b	Terrestial Plant Test: Vegetative Vigour Test Study code number G-65-20 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Pszczyna, 2021 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 5.1.2	Marcin Świstak	2021	Validation of analytical method for the determination of active substances – mesotrione and florasulam in aqueous solution of the test item MEZOFLOR 103 SC Study code number: 0030/0016/FA	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
			Sorbolab Sp. z o.o. Poznań, 2021 GLP Unpublished				
KCP 5.1.2	Magdalena Czar-nynoga	2024	MEZOFLOR 103 SC Collembolan (*Folsomia candida*) Reproduction Test Study code number G-44-24 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Pszczyna, 2024 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 5.1.2	Małgorzata Gór-ska	2024	MEZOFLOR 103 SC Predatory mite (*Hypoaspis (Geolaelaps) aculeifer*) reproduction test in soil Study code number G-45-24 Łukasiewicz Research Network - Institute of Industrial Organic Chemistry Pszczyna, 2024 GLP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Adam Sze-mandera	2020	Efficacy of MEZOFLOR 103 SC on weed control in maize. Poland 2020. 276 01 F20 472 Fertico Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Adam Sze-mandera	2020	Efficacy of MEZOFLOR 103 SC on weed control in maize. Poland 2020. 276 01 F20 473 Fertico Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Adam Sze-mandera	2020	Efficacy of MEZOFLOR 103 SC on weed control in maize. Poland 2020.	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
			276 01 F20 474 Fertico Sp. z o.o. GEP Unpublished				o.o
KCP 6.2; 6.4	Adam Sze-mandera	2020	Efficacy of MEZOFLOR 103 SC on weed control in maize. Poland 2020. 276 01 F20 475 Fertico Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Adam Sze-mandera	2020	Efficacy of MEZOFLOR 103 SC on weed control in maize. Poland 2020. 276 01 F20 476 Fertico Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Mateusz Kraw-czuk	2021	Efficacy evaluation of MEZOFLOR 103 SC applied into maize for the control of weeds. SGS/2021/073/PL01 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Mateusz Kraw-czuk	2021	Efficacy evaluation of MEZOFLOR 103 SC applied into maize for the control of weeds. SGS/2021/073/PL02 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Mateusz Kraw-czuk	2021	Efficacy evaluation of MEZOFLOR 103 SC applied into maize for the control of weeds. SGS/2021/073/PL03 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2; 6.4	Mateusz Kraw-czuk	2021	Efficacy evaluation of MEZOFLOR 103 SC applied into maize for the control of weeds. SGS/2021/073/PL04 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Mateusz Kraw-czuk	2021	Efficacy evaluation of MEZOFLOR 103 SC applied into maize for the control of weeds. SGS/2021/073/PL05 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Mateusz Kraw-czuk	2021	Efficacy evaluation of MEZOFLOR 103 SC applied into maize for the control of weeds. SGS/2021/073/PL06 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Adrian Luboiński	2021	Registration expertise in the scope of testing efficacy of herbicide MEZOFLOR 103 SC applied in maize. SH21KU103W Institute of Plant Protection-National Research Institute. Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Adrian Luboiński	2021	Registration expertise in the scope of testing efficacy of herbicide MEZOFLOR 103 SC applied in maize. SH21KU104W Institute of Plant Protection-National Research Institute. Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2; 6.4	Adrian Luboiński	2021	Registration expertise in the scope of testing efficacy of herbicide MEZOFLOR 103 SC applied in maize. SH21KU105W Institute of Plant Protection-National Research Institute. Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Łukasz Siekaniec	2021	Registration expertise in the scope of testing efficacy of herbicide MEZOFLOR 103 SC applied in maize. SH21KU106Z Institute of Plant Protection-National Research Institute. Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Łukasz Siekaniec	2021	Registration expertise in the scope of testing efficacy of herbicide MEZOFLOR 103 SC applied in maize. SH21KU107Z Institute of Plant Protection-National Research Institute. Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Łukasz Siekaniec	2021	Registration expertise in the scope of testing efficacy of herbicide MEZOFLOR 103 SC applied in maize. SH21KU108Z Institute of Plant Protection-National Research Institute. Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Adam Sze-mandera	2020	Selectivity of MEZOFLOR 103 SC applied on weed control in maize. Poland 2020.	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
			276 01 F20 477 Fertico Sp. z o.o. GEP Unpublished				o.o
KCP 6.2; 6.4	Adam Sze-mandera	2020	Selectivity of MEZOFLOR 103 SC applied on weed control in maize. Poland 2020. 276 01 F20 478 Fertico Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Mateusz Kraw-czuk	2021	Field study to evaluate the selectivity of MEZOFLOR 103 SC applied to maize. SGS/2021/074/PL01 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Mateusz Kraw-czuk	2021	Field study to evaluate the selectivity of MEZOFLOR 103 SC applied to maize. SGS/2021/074/PL02 SGS Polska Sp. z o.o. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Adrian Luboiński	2021	Registration expertise in the scope of testing phytotoxicity of herbicide MEZOFLOR 103 SC applied in maize. FH21KU109W Institute of Plant Protection-National Research Institute. Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos Agro Sp. z o.o
KCP 6.2; 6.4	Adrian Luboiński	2021	Registration expertise in the scope of testing phytotoxicity of herbicide MEZOFLOR 103 SC applied in maize. FH21KU110W Institute of Plant Protection-National Research Institute.	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protec-tion claimed Y/N	Justification if data protection is claimed	Owner
			Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP Unpublished				
KCP 6.2; 6.4	Sławomir Drzewiecki	2022	Biological efficacy expertise of herbicide Mezoflor 103 SC for mono and dicotyledonous weeds control in maize. 7 H/2022 Institute of Plant Protection – National Research Institute, Sosnicowice Branch. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 6.2; 6.4	Jacek Rogowski	2022	Expertise of the efficacy of herbicide Mezoflor 103 SC in the control of weeds in maize. (Registration study) 110/2022 Institute of Plant Protection-National Research Institute. Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 6.2; 6.4	Łukasz Siekaniec	2022	Expertise of the efficacy of herbicide Mezoflor 103 SC in the control of weeds in maize. (Registration study) 111/2022 Institute of Plant Protection-National Research Institute. Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 6.2; 6.4	Łukasz Siekaniec	2022	Expertise of the efficacy of herbicide Mezoflor 103 SC in the control of weeds in maize. (Registration study) 112/2022 Institute of Plant Protection-National Research Institute. Research Centre for Registration of Agrochemicals Herbicide Research Team. GEP	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 7.1.4	Krakowian D.	2021	MEZOFLOR 103 SC: *In vitro* Skin Corrosion: Reconstructed Human Epidermis Test Method. Study code: SCT-1/21. Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data never submitted in Poland	Synthos Agro Sp. z o.o.
KCP 7.1.5	[redacted]	2021	[redacted] Chemicals Not Requiring Classifications for Eye Irritation or Serious Eye Damage. Study code: ICE-01/21. Institute of Industrial Organic Chemistry, Branch Pszczyna GLP Unpublished	N	Y	Data never submitted in Poland	Synthos Agro Sp. z o.o.
KCP 10.1.2	[redacted]	2013	Generic field study on small mammals focal species and wood mouse (*Apodemus sylvaticus*) PT in maize fields in Germany. Rifcon GmbH. Oxon [redacted] GLP, Unpublished	Y	Y	Study report never submitted in Poland	Oxon Italia, S.p.A.,
KCP 10.2	Czarnecka Małgorzata	2021	MEZOFLOR 103 SC *Daphnia magna*, Acute Immobilisation Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W-56-20 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.2	Czarnecka Małgorzata	2021	MEZOFLOR 103 SC Lemna gibba CPCC 310, Growth inhibition test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W-59-20 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.2	Nierzędska Ewa	2021	MEZOFLOR 103 SC *Raphidocelis subcapitata* SAG 61.81 (formerly *Pseudokirchneriella subcapitata*), Growth inhibition test Łukasiewicz Research Network – Institute of Industrial Organic	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z

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			Chemistry, Branch Pszczyna Study code: W-57-20 GLP, Unpublished				o.o.
KCP 10.2	Nierzędska Ewa	2021	MEZOFLOR 103 SC *Navicula pelliculosa* SAG 1050-3, Growth inhibition test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: W-58-20 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.2	[redacted]	2021	[redacted] GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.3.1.1.1	Kulec-Płoszczyca Elżbieta	2021	MEZOFLOR 103 SC Honeybees (*Apis mellifera* L.), Acute Oral Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-17-21 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.3.1.1.2	Kulec-Płoszczyca Elżbieta	2021	MEZOFLOR 103 SC Honeybees (*Apis mellifera* L.), Acute Contact Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-18-21 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.3.1.1.3	Kulec-Płoszczyca Elżbieta	2021	MEZOFLOR 103 SC Bumblebees (Bombus spp.), Acute Oral Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-19-21 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.3.1.1.4	Kulec-Płoszczyca Elżbieta	2021	MEZOFLOR 103 SC Bumblebees (Bombus spp.),, Acute Contact Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-20-21 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.3.1.2	Kulec-Płoszczyca	2021	MEZOFLOR 103 SC Honeybees (*Apis mellifera* L.), Chronic Oral	N	Y	Study report never submitted in	Synthos

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	Elżbieta		Toxicity Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-16-21 GLP, Unpublished			Poland	AGRO Sp z o.o.
KCP 10.3.1.3	Orzechowska Urszula	2021	Honey Bee Larval Toxicity Test following Repeated Exposure to the test item MEZOFLOR 103 SC according to OECD GD 239 ENV/JM/MONO(2016)34 SORBOLAB Research Laboratory LLC Study code: 0030/0017/E GLP, Unpubished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.3.2	Kulec-Płoszczyca Elżbieta	2021	A laboratory test for evaluating the effects of MEZOFLOR 103 SC on the predatory mite, *Typhlodromus pyri* (Sch.) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-14-21 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.3.2	Kulec-Płoszczyca Elżbieta	2021	A laboratory test for evaluating the effects of MEZOFLOR 103 SC on the parasitic wasp, *Aphidius rhopalosiphi* (De Stefani - Perez) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: B-15-21 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.4	Pieczka Paweł	2021	MEZOFLOR 103 SC Earthworm reproduction test (Eisenia andrei) Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G-63-20 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.
KCP 10.5	Wołany Magdalena	2021	MEZOFLOR 103 SC Soil Microorganisms: Nitrogen Transformation Test Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna Study code: G-64-20 GLP, Unpublished	N	Y	Study report never submitted in Poland	Synthos AGRO Sp z o.o.

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

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KCP 5.2	Bacher, R.	2011a	Florasulam: Independent Laboratory Validation of a Residue Method for the Determination of florasulam in Agricultural Commodities Dow AgroSciences, Report no. 110536 GLP, unpublished	N	N	-	Dow AgroSciences
KCP 5.2	Bacher, R.	2011b	Method Validation Study for the Determination of Residues of Florasulam and its 5-OH Metabilite in Soil by Liquid Chromatography with Tandem Mass Spectrometry Dow AgroSciences, Report no. 110537 GLP, unpublished	N	N	-	Dow AgroSciences
KCP 5.2	Bacher, R.	2011c	Method Validation Study for the determination of Residues of Florasulam in Foodstuffs of Animal Origin by Liquid Chromatography with Tandem Mass Spectrometry Dow AgroSciences, Report no. 110540 GLP, unpublished	N	N	-	Dow AgroSciences
KCP 5.2	Class, T.	2011a	Method Validation Study for the Determination of Residues of Florasulam and its 5-OH Metabolite in Surface Water, Ground Water and Drinking Water by Liquid Chromatography with Tandem Mass Spectrometry Dow AgroSciences, Report no. 110538 GLP, unpublished	N	N	-	Dow AgroSciences
KCP 5.2	Watson G.	2013b	Validation of the QuEChERS Method for the Determination of Residues of mesotrione in Animal Matrices by LC-MS/MS Syngenta Eurofins Agroscience Services Ltd, Wilson,	N	N	-	Syngenta

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			UK, S12-03250 GLP not published Syngenta File No ZA1296_10093				
KCP 5.2	Bernal J.	2013	Mesotrione - Independent Laboratory Validation of the QuEChERS Method for the Determination of Residues of Mesotrione in Animal matrices by LC-MS/MS Syngenta Eurofins Agroscience Services Chem SAS, Vergèze, France, S12-04608 GLP not published Syngenta File No ZA1296_10130	N	N	-	Syngenta
KCP 5.2	Class, T.	2011b	The Development and Validation of a Method for the Analysis of Florasulam in Air Dow AgroSciences, Report no. 110282 GLP, unpublished	N	N	-	Dow AgroSciences
KCP 5.2	Class, T., Göcer, M.	2011	Florasulam: Development of an Analytical Method for the determination of Florasulam in Body Fluid(s) Dow AgroSciences, Report no. 110283 GLP, unpublished	N	N	-	Dow AgroSciences
KCP 5.2	Crook S.	2002	Mesotrione: Residue Analytical Method for the Determination of Residues of Mesotrione and 4-(Methylsulfonyl)-2-Nitrobenzoic Acid (MNBA) in Crop Samples Syngenta Crop Protection	N	N	-	Syngenta
KCP 5.2	Jutsum L.	2013a	Mesotrione – Validation of Draft Residue Method for the Determination of Mesotrione and its metabolites AMBA and MNBA in Water CEMAS, North Ascot, UK Syngenta File No ZA 1296_10087	N	N	-	Syngenta
KCP 5.2	Jutsum L., Chamkesam N.	2013	Mesotrione – Analytical Method GRM007.09A for the determination of	N	N	-	Syngenta

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			mesotrione and its Metabolites AMBA and MNBA in water CEMAS, North Ascot, UK Syngenta File No ZA 1296_10091				
KCP 5.2	Jutsum L., Wil-liams R.	2013	Mesotrione – Analytical Method GRM007.10A for the determination of Mesotrione and its Metabolites AMBA and MNBA in Soil CEMAS, Noth Ascot UK Syngenta File ZA1296_10092	N	N	-	Syngenta
KCP 5.2	Lindner M.,	2011	Examination of the applicability of the Modular Analytical Method L 00.00-34 for the determination of Residues of Florasulam Dow AgroSciences, Report no. 110671 GLP, unpublished	N	N	-	Dow AgroSciences
KCP 5.2	Robaugh, D.A.	2011	Independent Laboratory Validation Study for the determination of Residues of Florasulam in Bovine and Poultry Tissues by Liquid Chromatography with Tandem Mass Spectrometry Dow AgroSciences, Report no. 110541 GLP, unpublished	N	N	-	Dow AgroSciences
KCP 5.2	Rodrigues Junior, A.	2011	Residue Method Validation for the Determination of Florasulam in Agricultural Commodities Dow AgroSciences, Report no. 110535 GLP, unpublished	N	N	-	Dow AgroSciences
KCP 5.2	Souza, N.	2011	Independent Laboratory Validation of Dow AgroSciences LLC Method – Determination of Residues of Florasulam and its 5-OH Metabolite in Drinking Water, Ground Water and Surface Water by Liquid Chromatography with Tandem Mass Spectrometric Detection	N	N	-	Dow AgroSciences

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			Dow AgroSciences, Report no. 110539 GLP, unpublished				
KCA 6.1. (7.2.1.)	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	-	Syngenta
KCA 6.1. (7.2.1.)	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	-	Syngenta
KCA 6.2. (7.2.2.)	Wei, Y. et al	1997	[Cyclohexane-2-14C]ZA 1296: Nature of the Residues in Corn (Zea mays). Zeneca Agrochemicals Report : RR 96-026B	N	N	-	Syngenta
KCA 6.2. (7.2.2.)	Tarr, J.B. et al	1997	[Phenyl-U-14C]ZA 1296: nature of the resi-dues in corn.	N	N	-	Syngenta
KCA 6.2. (7.2.2.)	Brumback D.	2003	[Cyclohexane-2-^{14}C] Mesotrione: Nature of the Residue in Peanuts. Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001287-01 1287-01 GLP, not published Syngenta File No ZA1296/1350	N	N	-	Syngenta
KCA 6.2. (7.2.2.)	Brown K.	2003	[Phenyl-U-14C] Mesotrione: Nature of the Residue in Peanuts. Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection, Inc., Greensboro, USA, T001286-01 1286-01 GLP, not published Syngenta File No ZA1296/1349	N	N	-	Syngenta
KCA 6.2. (7.2.2.)	Dohn D., Chu J.	2012	14C-Mesotrione - Nature of the Residue in Herbicide Tolerant (HT) Soybeans. Syngenta PTRL West, Hercules CA, USA,	N	N	-	Syngenta

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			Syngenta Crop Protection, LLC, Greensboro, NC, USA, Landis International, Valdosta, USA, Agvise Laboratories, Northwood, ND, USA, 1943W, 860.1300-09-433-07B-03 GLP, not published Syngenta File No ZA1296_50531				
KCA 6.2. (7.2.2.)	Unknown	1997	AMBA: Metabolism of Orally Administrated Multiple doses in Lactating Cow.	N	N	-	Syngenta
KCA 6.3. (7.2.3.)	Barnes J.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in France During 1995 (WRC-96099) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 96-071B GLP, not published Syngenta File No ZA1296/0412	N	N	-	Syngenta
KCA 6.3. (7.2.3.)	Barnes J.	1997a	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1995 (WRC-96114) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 96-078B GLP, not published Syngenta File No ZA1296/0409	N	N	-	Syngenta
KCA 6.3. (7.2.3.)	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	-	Syngenta
KCA 6.3. (7.2.3.)	Miller M., Atger J., Wiebe L., Elvira D.	1998	ZA1296: Residue Levels in Maize from Trials Carried out in France During 1996 (Pre-emergence) (WRC-97-138) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-062B GLP, not published Syngenta File No ZA1296/0417	N	N	-	Syngenta

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KCA 6.3. (7.2.3.)	Miller M., Griehl T., Wiebe L., Elvira D.	1998	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Preiemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-063B GLP, not published Syngenta File No ZA1296/0418	N	N	-	Syngenta
KCA 6.3. (7.2.3.)	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	-	Syngenta
KCA 6.3. (7.2.3.)	Klimmek S., Gizler A.	2008	MESOTRIONE AND NICOSULFURON: RESIDUE STUDY ON MAIZE IN NORTHERN FRANCE IN 2007. Syngenta - Jealott's Hill, Bracknell, United Kingdom Eurofins - Dr Specht & Partner, Hamburg, Germany, T011368-07 GLP, not published Syngenta File No A14351BX_10205	N	N	-	Syngenta
KCA 6.3. (7.2.3.)	Heillaut C.	2009	Glyphosate (ASF71), Mesotrione (ZA1296) and S-Metolachlor (CGA77102) - Residue Study on GA21 (MON-ØØØ21-9) Corn in France (North) and Czech Republic in 2007. Syngenta ADME - Bioanalyses, Vergeze, France, T01108506 GLP, not published Syngenta File No A15189G_10009	N	N	-	Syngenta
KCA 6.3. (7.2.3.)	Schulz H	2010	Mesotrione and Nicosulfuron - Residue Study on Maize in France (North) in 2008. Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T009530-07REG	N	N	-	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro-tection is claimed	Owner
			GLP, not published Syngenta File No ZA1296_10049				
KCA 6.3. (7.2.3.)	Heillaut C.	2009a	Glyphosate, Mesotrione and S-Metolachlor Residue Study on GA21 (MON-00021-9) Corn in Denmark and Sweden in 2008. Syngenta ADME - Bioanalyses, Vergeze, France, T00953307-REG GLP, not published Syngenta File No A15189G_10014	N	N	-	Syngenta
KCA 6.3. (7.2.3.)	Meyer M.	2011	Mesotrione - Residue Study on Field Corn in Germany and the United Kingdom in 2009. Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T000920-09REG GLP, not published Syngenta File No A14203B_10105	N	N	-	Syngenta
KCA 6.6.1 (7.2.2.2.)	Spillner, C. et al	1997	[Cyclohexane-2-14C]ZA 1296: confined accumulation studies on rotational crops – low rate	N	N	-	Syngenta
KCA 6.6.1 (7.2.2.2.)	Gorder, G.W. et al	1997	[Phenyl-U-14C]ZA 1296: confined accumulation studies on rotational crops – low rate	N	N	-	Syngenta
KCA 6.6.1 (7.2.2.2.)	Barnes, J.P., Wiebe, L.A.	1997	ZA 1296: Residue Levels on Rotated Crops from Trials Carried Out in the United States During 1995-1996. Zeneca Report No:RR 97-044B	N	N	-	Syngenta
KCA 6.1. (7.3.1.)	Butler, RE, Gam-bie, A.	1997	The Stability of DE-570 in Wheat Under Frozen Storage Conditions over 18 months (Interim Report) ST96-001 DowElanco Europe, Letcombe Regis, Oxon, UK GLP Unpublished	N	N	-	Dow AgroSciences

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KCA 6.1. (7.3.1.)	Gambie, A, Teasdale R.	1999	The Stability of DE-570 in Wheat Under Frozen Storage Conditions over 18 months (Final Report) ST96-001 DowElanco Europe, Letcombe Regis, Oxon, UK GLP Unpublished	N	N	-	Dow AgroSciences
KCA 6.2. (7.3.2)	Pillar, F.	1997	The Metabolism of XDE-570 in Winter Wheat - Final Report 5U DowElanco Europe, Letcombe Regis, Oxon, UK GLP Unpublished	N	N	-	Dow AgroSciences
KCA 6.2. (7.3.2)	Unknown	1994	Nature of the Residue of [14C] XDE-570 in Laying Hens MET 94018 [redacted] GLP Unpublished	N	N	-	Dow AgroSciences
KCA 6.2. (7.3.2)	Unknown	1994	Nature of the Residue of [14C]XDE-570 in Lactating Goats MET94017 [redacted] GLP Unpublished	N	N	-	Dow AgroSciences
KCA 6.2. (7.3.2)	MacDonald, A.	1997	The uptake of XDE-570 into Four Seeceeding Crops 7U DowElanco Europe, Letcombe Regis, Oxon, UK GLP Unpublished	N	N	-	Dow AgroSciences
KCA 6.3. (7.3.3.)	Proiner, I.	2011	Residues of florasulam in sweet corn at harvest and at intervals following a single application of EF-1343, Northern and Southern Europe – 2010. Dow AgroSciences, European Development Centre	N	N	-	Dow AgroSciences

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro-tection is claimed	Owner
			Report number: GHE-P-12645 GLP Unpublished				
KCA 6.3. (7.3.3.)	Proiner, I.	2012	Residues of florasulam in maize at harvest and at intervals following a single application of EF-1343. Northern and Southern Europe – 2011. Dow AgroSciences, European Development Centre Report number: GHE-P-12800 GLP Unpublished	N	N	-	Dow AgroSciences
KCA 7.1 / 01	Fish L.	2013	GIS study of the proportion of acid and alka-line soils under maize crop in Europe Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ1012B Not GLP, not published Syngenta File No ZA1296_10160 This is CONFIDENTIAL INFORMATION	N	N	-	Syngenta
KCA 7.1.2 (IIA 7.1.1)	Lay, M.M	2000	[Phenyl-U-14C] AMBA : Rate of Degradation in Soil under Aerobic Laboratory Conditions Zeneca Ag products Western Research Center Report No RR 99-096B	N	N	-	Syngenta
IIA 7.1.1.1.1/01, IIA 7.1.1.2.1/ 01 (OECD Annex IIA point: 7.1, 7.2,)	Jackson R., Ghosh D.,	1997	The Aerobic Degradation of XDE-570 in Soil.; DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Report No. GHE-P-4710; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
KCA 7.1.2 (II,	Vispetto, A.R., Tovshteyn, M.	1997	Addendum to: [Cyclohexane-2-14C]ZA 1296. Aerobic soil metabolism study.	N	N	-	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro-tection is claimed	Owner
7.1.1.1.1/01)			Zeneca Agrochemicals Report No: RR95-047B ADD				
IIA 7.1.1.1.1/02, IIA 7.1.1.2.1/ 02 (OECD Annex IIA point: 7.1, 7.2,)	Jackson R., Mas-sart J.,	1998	The degradation of DFP-ASTCA and ASTCA (two metabolites of DE-570) in Soil.; Dow AgroSciences, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Report No. GHE-P-7522; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
KCA 7.1.2 (II, 7.1.1.1.1/02)	Subba-Rao, R.V.	1996	[Phenyl 14C-ZA 1296. Aerobic soil metabo-lism study. Zeneca Agrochemicals Report No: RR95-082B	N	N	-	Syngenta
KCA 7.1.1 & 7.1.2 (II, 7.1.1.1.1/03)	Miller, M.M.	1997	[Phenyl-U-14C]ZA 1296: Route and Rate of Degradation in Wisconsin Silt Loam Soil Un-der Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-033B	N	N	-	Syngenta
IIA 7.1.1.1.2/01 IIA 7.1.1.2.1/ 07 (OECD Annex II point: 7.1.2)	Cleveland C. B., Sanders L. T., Gilbert J. R.,	1997	Anaerobic Aquatic Metabolism Study of XDE-570.; North American Environmental Chemistry Laboratory, DowElanco, 9330 Zionsville Road, Indianapolis, Indiana 46268-1053, USA; Study report No. ENV95137; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
KCA 7.1.1.2 / 01	Hand L.	2013	Mesotrione - Assessment of the significance of unidentified components from harsh extraction of soil residues in 14C-cyclohexanedione la-belled mesotrione soil metabolism studies Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom,	N	N	-	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Not GLP, not published Syngenta File No ZA1296_10185 This is CONFIDENTIAL INFORMATION				
KCA 7.1.2 (II, 7.1.1.2.1/02)	Tarr, J.B.	1997	[phenyl-U-14C]ZA 1296. Metabolism in Thirteen Soils Under Aerobic Conditions. Zeneca Agrochemicals Report No: RR93-092B	N	N	-	Syngenta
KCA 7.1.2 (II, 7.1.1.1.2/01)	Vispetto, A.R., Tovshteyn, M.	1996	[cyclohexane-2-14C]ZA 1296. Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR95-048B	N	N	-	Syngenta
KCA 7.1.2 (II, 7.1.1.1.2/02)	Carley, S.E.	1996	[phenyl-U-14C]ZA 1296 Anaerobic Aquatic Soil Metabolism. Zeneca Agrochemicals Report No: RR96-033B	N	N	-	Syngenta
IIA 7.1.1.1.2/02 (OECD Annex II point: 7.1.3)	Krieger M. S., Yoder R. N.,	1996	Photolysis of XDE-570 on Soil.; Global Environmental Chemistry Laboratory – Indianapolis Lab, DowElanco, 9330 Zionsville Road, Indianapolis, Indiana 46268-1053, USA; Study report No. ENV95083; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
KCA 7.1.2.1.1 / 01	Hardy I.	2013	Mesotrione - Kinetic Modelling Analysis of Data from Aerobic Soil Degradation Studies to Derive Modelling and Persistence Endpoint DT50 Values Syngenta Battelle UK Ltd., Ongar, United Kingdom, NC/11/059C Not GLP, not published Syngenta File No ZA1296_10135 This is CONFIDENTIAL INFORMATION	N	N	-	Syngenta
KCA 7.1.2 (II,	Miller, M.M., Wilson, W.R.	1997	[phenyl-U-14C]ZA 1296. Rate of Degradation in Three Soils Under Aerobic Laboratory	N	N	-	Syngenta

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7.1.1.2.1/01)			Condition. Zeneca Agrochemicals Report No: RR96-099B				
IIA 7.1.1.2.1/ 03 (OECD Annex IIA point: 7.2)	Pillar F.,	1997	Effects of temperature on the degradation of DE-570 in soil.; DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6749; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
KCA 7.1.2 (II, 7.1.1.2.1/04)	Marth, J.L.	1997	[14C]AMBA, a Metabolite of ZA 1296: Rate of Degradation in Soil Under Aerobic Laboratory Conditions. Zeneca Agrochemicals Report No: RR97-032	N	N	-	Syngenta
IIA 7.1.1.2.1/ 04 (OECD Annex IIA point: 7.2)	Pillar F.,	1997a	Effects of moisture on the degradation of DE-570 in soil.; DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6750; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.1.1.2.1/ 05 (OECD Annex IIA point: 7.2)	Jackson R.,	2010	Re-evaluation of the Degradation Kinetics of Florasulam and its Major Metabolites in European Soils According to Focus Guidance.; Dow AgroSciences, European Development Centre, 3 Milton Park, Abingdon, OX14 4RN, UK; Report No GHE-P-12511; GLP: no, not required (modelling study); Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.1.1.2.1/ 06	Simmonds R.,	2012	[14C]-TSA: Rate of Degradation in Four Soils at 200C.;	No	N	-	Dow AgroSciences

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro-tection is claimed	Owner
(OECD Annex IIA point: 7.2)			Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow Agro-Sciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/010; GLP: Yes; Unpublished report				
KCA 7.1.2.2 (II, 7.1.1.2.2/01 III, 9.2.2.2/01)	Graham, D.G. et al	1997a	Field Soil Dissipation Study Carried Out in France During 1995-1996. Zeneca Agrochemicals Report No: RR97-026B	N	N	-	Syngenta
KCA 7.1.2.2 (II, 7.1.1.2.2/02 III, 9.2.2.2/02)	Graham, D.G. et al	1997b	Field Dissipation Study Carried Out in Italy During 1995-1996. Zeneca Agrochemicals Report No: RR97-025B	N	N	-	Syngenta
KCA 7.1.2.2 (II, 7.1.1.2.2/03 III, 9.2.2.2/03)	Graham, D.G. et al	1997c	Field Dissipation Study Carried Out in Germany During 1995-1996. Zeneca Agrochemicals Report No: RR97-051B	N	N	-	Syngenta
KCA 7.1.2.2 (II, 7.1.1.2.2/04 III, 9.2.2.2/04)	Graham, D.G. et al	1998a	Field Dissipation Study Carried Out in Germany During 1996-1997. Zeneca Agrochemicals Report No: RR97-067B	N	N	-	Syngenta
KCA 7.1.2.2 (II, 7.1.1.2.2/05 III, 9.2.2.2/05)	Graham, D.G. et al	1998b	Field Dissipation Study Carried Out in Italy During 1996-1997. Zeneca Agrochemicals Report No: RR97-070B	N	N	-	Syngenta
IIA	Maycock R.	1997	The dissipation of XDE-570 and its 5-hydroxy	No	N	-	Dow AgroSciences

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7.1.1.2.2/ 01 (OECD Annex IIA point: 7.3.1)			metabolite in soil at intervals following a sin-gle application of EF-1343, Germany, 1995 – 1996.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6366; GLP: Yes; Unpublished report				
IIA 7.1.1.2.2/ 02 (OECD Annex IIA point: 7.3.1)	Maycock R.	1997a	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a sin-gle application of EF-1343, Northern France - 1995.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6367; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.1.1.2.2/ 03 (OECD Annex IIA point: 7.3.1)	Maycock R.	1997b	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a sin-gle application of EF-1343, UK – 1996.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6368; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.1.1.2.2/ 04 (OECD Annex IIA point: 7.3.1)	Maycock R.	1997c	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a sin-gle application of EF-1343, Southern France - 1996.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6369; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences

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IIA 7.1.1.2.2/ 05 (OECD Annex IIA point: 7.3.1)	Maycock R.	1997d	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a sin-gle application of EF-1343, Greece - 1996.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6370; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.1.1.2.2/ 06 (OECD Annex IIA point: 7.3.1)	Maycock R.	1997e	The dissipation of XDE-570 and its 5-hydroxy metabolite in soil at intervals following a sin-gle application of EF-1343, UK - 1995.; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6781; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
KCA 7.1.2.2 (II, 7.1.1.2.2/06)	Wiebe, L.A., Yeh, S. M.	1999	ZA 1296: Stability of ZA 1296 and the metab-olites MNBA and AMBA in Frozen Soil (WRC-98-158). (WINO 12775). Zeneca Agrochemicals Report No: RR98-065B	N	N	-	Syngenta
IIA 7.1.1.2.2/ 07 (OECD Annex IIA point: 7.3.2)	Gambie A.,	1997	Residues of DE-570 and its 5-hydroxy me-tabolite in soil at normal harvest following application of EF-1343 to wheat and barley – Europe: 1995-1996"; Dow Elanco Europe, Letcombe Regis, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6833; GLP: No; Unpublished report;	No	N	-	Dow AgroSciences
KCA 7.1.3 (IIA 7.1.2)	Hand, L.H	1999a	MNBA (R169649) : Absorption Properties in Four Soils Zeneca Agrochemicals Jealott's Hill Research Station	N	N	-	Syngenta

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			Report No RJ2885B				
KCA 7.1.3 (II, 7.1.2/01)	Diaz, D.G.	1995	[14C]ZA 1296. Adsorption and Desorption Properties in Soil. Zeneca Agrochemicals Report No: RR95-070B	N	N	-	Syngenta
KCA 7.1.3 (II, 7.1.2/02)	Rowe, D., Lane, M.C.G.	1997a	ZA 1296: Adsorption and Desorption properties of ZA 1296 in 4 soils. Zeneca Agrochemicals Report No: RJ2340B	N	N	-	Syngenta
KCA 7.1.3 (II, 7.1.2/04)	Diaz, D.G.	1996a	[14C]MNBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-008B	N	N	-	Syngenta
KCA 7.1.3 (II, 7.1.2/05)	Diaz, D.G.	1996b	[14C]AMBA. Adsorption and Desorption Properties in Soil of a ZA 1296 Metabolite. Zeneca Agrochemicals Report No: RR96-009B	N	N	-	Syngenta
IIA 7.1.2/01 (OECD Annex IIA points: 7.4.1 and 7.4.2)	Ostrander J. A.	1996	Mobility Studies of XDE-570 and 5-hydroxy-XDE 570;. North American Environmental Chemistry Laboratory, Dow Elanco, 9330 Zionsville Road, Indianapolis, Indiana 46268-1053, USA; Study report No. GH-C-3868 (study ID: ENV95020); GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.1.2/02 (OECD Annex IIA point: 7.4.2)	Simmonds R.	2011	Florasulam: Adsorption and Desorption Properties of [14C]-Florasulam in Eight Soils.; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/005; GLP: Yes;	No	N	-	Dow AgroSciences

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			Unpublished report;				
IIA 7.1.2/03 (OECD Annex IIA point: 7.4.2)	Simmonds R.	2011a	Florasulam: Adsorption Properties of [14C]-5-hydroxyflorasulam in Four Soils.; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/006; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.1.2/04 (OECD Annex IIA point: 7.4.2)	Burgess M., Simmonds R.,	2011	Florasulam: Adsorption Properties of [14C]-DFP-ASTCA in Four Soils.; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/009; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.1.2/05 (OECD Annex IIA point: 7.4.2)	Burgess M., Simmonds R.,	2011b	Florasulam: Adsorption Properties of [14C]-ASTCA in Four Soils.; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road, Ongar, Essex CM5 0GZ, UK *for* Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/008; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.1.2/06 (OECD Annex IIA point: 7.4.2)	Burgess M., Simmonds R.,	2011c	Florasulam: Adsorption Properties of [14C]-TSA in Four Soils.; Battelle UK Ltd., Battelle House, Fyfield Business and Research Park, Fyfield Road,	No	N	-	Dow AgroSciences

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			Ongar, Essex CM5 0GZ, UK *for* Dow Agro-Sciences, 3 Milton Park, Abingdon, Oxon, UK; Study report No. YR/11/007; GLP: Yes; Unpublished report;				
IIA 7.1.3.1 (OECD Annex IIA point: 7.4.3)	Pillar F.	1997	The non-aged column leaching of DE-570.; DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Study report No. GHE-P-6785; GLP: No; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.1.3.3; IIIA 9.1.2.2; (OECD Annex IIA point: 7.4.7)	Jackson R., Pat-erson G.,	1997	The dissipation of XDE-570 in soil and crops using field lysimeters.; DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Study report No. GHE-P-6751; GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.2.1.1/01 (OECD Annex IIA points: 2.9.1 and 7.5)	Jackson R., Portwood D.,	1993	The Aqueous Hydrolysis of XR-570.; DowElanco Limited, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Study report No. GHE-P-3326; GLP: No; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.2.1.1/02 (OECD Annex IIA points: 2.9.1 and 7.5)	Phillips M.,	1996	The determination of the hydrolytic stability of radiolabelled XDE-570.; Inveresk Research International Ltd., Tranent, EH33 2NE, UK *for* DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Study report	No	N	-	Dow AgroSciences

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			No. GHE-P-4986 (Inveresk Project No. 386209); GLP: Yes; Unpublished report				
IIA 7.2.1.2/01 (OECD Annex IIA points: 2.9.2 and 7.6)	Yoder R. N.	1996	Aqueous Photolysis of XDE-570 in Natural Sunlight.; DowElanco, North American Environmental Chemistry Laboratory, 9330 Zionsville Road, Indianapolis, Indiana 46268-1053, USA; Study report No. GH-C 3951 (study ID: ENV95023); GLP: Yes; Unpublished Report	No	N	-	Dow AgroSciences
IIA 7.2.1.2/02 (OECD Annex IIA points: 2.9.2 and 7.6)	Yoder R. N., Balcer J. L.	2002	Aqueous Photolysis of Florasulam in pH5 Buffer under Xenon Light.; Regulatory Laboratories – Indianapolis Lab, Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, USA; Study report No. GH-C 5399; GLP: Yes Unpublished report	No	N	-	Dow AgroSciences
IIA 7.2.1.2/03 (OECD Annex IIA points: 2.9.2 and 7.6)	Byrne S. L., Crabtree A. B., Balcer J. L., Linder S. J.	2005	Aqueous Photolysis of Florasulam in Natural Water Using a Xenon Lamp.; Regulatory Laboratories – Indianapolis Lab, Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268-1054, USA Study report No. 050024; GLP: Yes Unpublished report	No	N	-	Dow AgroSciences
IIA 7.2.1.2/04 (OECD Annex IIA points: 2.9.2	Gibson R., Portwood D.	1999	Investigation of the degradation of DE-570 in natural water.; Dow AgroSciences, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon OX12 9JT, UK;	No	N	-	Dow AgroSciences

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro-tection is claimed	Owner
and 7.6)			Study report No. GHE-P-7468; GLP: Yes; Unpublished report				
IIA 7.2.1.3.1/01 (OECD Annex IIA point 7.7)	Jenkins W. R.	1994	XDE 570 (PURE): Assessment of Ready Bio-degradability. Modified Sturm Test.; Pharmaco LSR Lts, Eye, Suffolk IP 23 7 PX, UK, *for* DowElanco Europe, Letcombe Labor-atory, Letcombe Regis, Wantage, Oxfordshire OX12 9JT, UK; Study report No. GHE-P-3736 (Pharmaco study report No.: 94/DES180/0468) GLP: Yes Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.2.1.3.1/02 (OECD Annex IIA point 7.7)	Jenkins W. R.	1995	XDE 570 5-Hydroxy6 metabolite: Assessment of Ready Biodegradability. Modified Sturm Test. Pharmaco LSR Lts, Eye, Suffolk IP 23 7 PX, UK, *for* DowElanco Europe, Letcombe Labor-atory, Letcombe Regis, Wantage, Oxfordshire OX12 9JT, UK; Study report No. GHE-P-4552 (Pharmaco study report No.: 95/DES284/0692); GLP: Yes; Unpublished report;	No	N	-	Dow AgroSciences
IIA 7.2.1.3.2/01 (OECD Annex IIA point 7.8.3)	Phillips M.	1997	The aerobic degradation of XDE-570 in natu-ral waters and associated sediments.; Inveresk Research International Ltd., Tranent, EH33 2NE, UK *for* DowElanco Europe, Letcombe Laboratory, Letcombe Regis, Wantage, Oxon, OX12 9JT, UK; Study report No. GHE-P-5039 (Inveresk Pro-ject No. 12712); GLP: Yes; Unpublished report	No	N	-	Dow AgroSciences

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IIA 7.2.1.3.2/02 (OECD Annex IIA point 7.8.3)	Lewis C., Gilbert J.,	2011	[14C]-Florasulam: Degradation in Water-Sediment Systems under Aerobic Conditions.; Covance Laboratories Ltd, Otley Road, Harrogate, HG3 1PY, UK for Dow AgroSciences, 3 Milton Park, Abingdon, Oxon, OX14 4RN, UK; Study report No. 1000576 (Covance Study No. 8235547); GLP: Yes Unpublished report	No	N	-	Dow AgroSciences
IIA 7.2.2/01 (OECD Annex IIA point 7.10)	Knoch E.,	1997	Investigation of the Volatilization of DE-570 formulated as 50 g a. s./L SC from soil and Dwarf Runner Bean.; Institut Fresenius, Chemische und Biologische Laboratorien GmbH, Konrad-Adenauer-Strasse 9-13, 45699 Herten, Germany *for* DowElanco Europe, Letcombe Laboratories, Wantage, Oxon OX12 9JT, UK; Study report No. GHE-P-6747 (Fresenius Institut Study No. IF 97/07970-00); GLP: Yes; Unpublished Report;	No	N	-	Dow AgroSciences
KCA 7.3 (II, 7.2.2/01)	Patel, A., Benner, J.	1997	ZA 1296: Volatilisation from Soil and Leaf Surfaces Following Application as a Suspension concentrate Formulation Containing a Build in Wetter. Zeneca Agrochemicals Report No: RJ2374B	N	N	-	Syngenta
IIA 7 (OECD Annex IIA point 7)	Mattock S. D.	2011	Florasulam – literature search for toxicology, environmental fate and ecotoxicology in support of Annex I renewal.; TGSA Concordia House, St James Business Park, Grimbald Crag Court, Knaresborough, North Yorkshire, UK, *for* Dow AgroSciences European R&D Centre, 3 Milton Park, Abing-	No	N	-	Dow AgroSciences

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro-tection is claimed	Owner
			don, Oxfordshire, UK; Study report No. GHE-P-12699 (Project num-ber 4-16-6); GLP: No, not required; Unpublished report;				
KCP 10.1	[redacted]	2005	Generic field monitoring of birds and mam-mals on maize and beet fields in Austria [redacted]	Y	N	-	---
KCP 10.1.1	[redacted]	1994	XDE-570 An acute Toxicity Study with the Japanese Quail	Y	N	-	Dow Agro Science
KCP 10.1.1	[redacted]	1995	XDE-570 A reproduction study with the Mallard (*Anas platyrhynchos*)	Y	N	-	Dow Agro Science
KCP 10.1.1	[redacted]	1995 b	Acute oral toxicity of mesotrione to *Colinus virginianus* GLP, not published	Y	N	-	---
KCP 10.1.1	[redacted]	1997 b	Reproductive toxicity of mesotrione to *Anas platyrhynchos* GLP, not published	Y	N	-	---
KCP 10.1.1	[redacted]	[redacted]	ZA1296 - Statistical Re-analysis: Effects on reproduction in mallard duck (Anas platyrhyn-chos) Syngenta Cambridge Environmental Assessments, Unit-ed Kingdom, CEA.1054 Not GLP, not published [redacted] This is CONFIDENTIAL INFORMATION	[redacted]	N	-	Syngenta
KCP 10.1.2	[redacted]	[redacted]	Two generation reproductive toxicity in the rat GLP, not published	Y	N	-	---
KCP 10.1.2	[redacted]	[redacted]	ZA1296: Acute oral toxicity to the rat GLP, not published	Y	N	-	Syngenta
KCP 10.1.2	[redacted]	[redacted]	Acute oral toxicity to the rat GLP, not published	Y	N	-	---

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KCP 10.1.2	[redacted]	[redacted]	ZA 1296: Multigeneration study in the rat GLP, not published	Y	N	-	Syngenta
KCP 10.2	[redacted]	[redacted]	Acute toxicity of mesotrione to *Oncorhynchus mykiss* GLP, not published	Y	N	-	Syngenta
KCP 10.2	[redacted]	[redacted]	Evaluation of the Acute Toxicity of XDE-570 Herbicide to the Rainbow Trout, Oncorhynchus mykiss Walbaum. [redacted] GLP, not published	Y	N	-	Dow Agro Science
KCP 10.2	[redacted]	[redacted]	Chronic toxicity of mesotrione to *Pinephales promelas* GLP, not published	Y	N	-	Syngenta
KCP 10.2	[redacted]	[redacted]	Acute toxicity of MNBA (97.1% purity) to *Oncorhynchus mykiss* GLP, not published	Y	N	-	Syngenta
KCP 10.2	[redacted]	[redacted]	Acute toxicity of AMBA (99% purity) to *Oncorhynchus mykiss* GLP, not published	Y	N	-	Syngenta
KCP 10.2	---	[redacted]	Florasulam technical: an early life-stage toxicity test with the fathead minnow (Pimephales promelas). Dow AgroSciences [redacted] GLP, unpublished	Y	N	-	Dow Agro Science
KCP 10.2	Dark R.	2013	ZA1296 - Statistical Re-analysis: Toxicity to the Green Alga Selenastrum capricornutum Syngenta tecsolve, North Ascot, United Kingdom, ZA1296/0214/1 Not GLP, not published Syngenta File No ZA1296_10173	N	N	-	Syngenta
KCP 10.2	Dark R.	2013a	MNBA - Statistical Re-analysis: Toxicity to the Green Alga Selenastrum capricornutum Syngenta	N	N	-	Syngenta

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			tecsolve, North Ascot, United Kingdom, ZA1296/0533/1 Not GLP, not published Syngenta File No CA3511_10008				
KCP 10.2	Dark R.	2013b	AMBA - Statistical Re-analysis: Toxicity to the Green Alga Selenastrum capricornutum Syngenta tecsolve, North Ascot, United Kingdom, AM-BA/0220/1 Not GLP, not published Syngenta File No R044276_10005	N	N	-	Syngenta
KCP 10.2	Gentle & Hamer	1995	Acute toxicity of mesotrione to *Daphnia magna* GLP, not published	N	N	-	Syngenta
KCP 10.2	Hancock G.A.	2007	5-Hydroxy-florasulam: growth inhibition test with the aquatic plant duckweed, *Lemna gibba* GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Kelly C.R.	1997	XDE-570: Toxicity to the sediment dwelling fhase of the midge *Chirinomus riparius*, GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Kent & Shillaber	1997	Acute toxicity of MNBA (97.1% purity) to *Daphnia magna* GLP, not published	N	N	-	Syngenta
KCP 10.2	Kirk H.D. et al.	1995	Evaluation of the acute toxicity of XDE-570 herbicide to the daphnid, Daphnia magna STRAUS GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Kirk H.D. et al.	1995	Evaluation of the acute toxicity of 5-hydroxy XDE-570 herbicide to the daphnid, Daphnia magna STRAUS GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Kirk H.D. et al.	1996	Evaluation of the chronic toxicity of XDE-570 herbicide to the daphnid, Daphnia magna STRAUS,	N	N	-	Dow Agro Science

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			GLP, unpublished				
KCP 10.2	Kirk H.D.	1998	Toxicity of metabolites of XDE-570 to *Daph-nia magna*. GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Kirk H.D. et al.	2000	5-(Aminosulfonyl)-1H-1,2,4-triazole-3-carboxylic acid (florasulam M4 metabolite): growth inhibition test with the freshwater aquatic plant, duckweed, *Lemna gibba* L. GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Kirk H.D. et al.	2000	5-(Aminosulfonyl)-1H-1,2,4-triazole-3-carboxylic acid (florasulam M4 metabolite): growth inhibition test with the freshwater green alga, *Selenastrum capricornutum* PRINTZ GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Liedtke A.	2013	ZA1296 - Statistical Re-analysis: Chronic Toxicity to Daphnia magna Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D79284 Not GLP, not published Syngenta File No ZA1296_10163	N	N	-	Syngenta
KCP 10.2	Liedtke A.	2013a	ZA1296 - Statistical Re-analysis: Toxicity to Lemna gibba Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D83053 Not GLP, not published Syngenta File No ZA1296_10164	N	N	-	Syngenta
KCP 10.2	Liedtke, A.	2013b	R44276 - Toxicity to the aquatic higher plant *Lemna gibba* in a 7-day growth inhibition test. Report Number D55614. Harlan Laboratories Ltd., Itingen, Switzerland	N	N	-	Syngenta

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro-tection is claimed	Owner
			GLP, not published				
KCP 10.2	Liedtke, A.	2013c	R169649 - Toxicity to the aquatic higher plant *Lemna gibba* in a 7-day growth inhibition test. Report Number D55592. Harlan Laboratories Ltd., Itingen, Switzerland. (	N	N	-	Syngenta
KCP 10.2	Liedtke, A.	2013d	SYN546974 - Toxicity to the aquatic higher plant Lemna gibba in a 7-day growth inhibi-tion test Syngenta Harlan Laboratories Ltd., Itingen, Switzerland, D77394 GLP, not published	N	N	-	Syngenta
KCP 10.2	Magor & Gore	1998	Acute toxicity of AMBA (99% purity) to *Daphnia magna* GLP, not published	N	N	-	Syngenta
KCP 10.2	Milazzo D.P.	1995	The toxicity of XDE-570 herbicide to aquatic plant, *Lemna gibba L.* G-3 GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Milazzo D.P., et al.	1995	XDE-570 herbicide: The toxicity to the green alga, *Selenastrum capricornutum* Printz GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Morris *et al.*	1996	Chronic toxicity of mesotrione to *Daphnia magna* GLP, not published	N	N	-	Syngenta
KCP 10.2	Porch J.R.	2011	Florasulam (TPSA metabolite): a 7-day static-renewal toxicity test with duckweed (*Lemna gibba* G3) GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Porch, J.R., et al.	2011	TPSA metabolite of florasulam: a 96-hour toxicity test with the freshwater alga (*Pseudo-kirchneriella subcapitata*). GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Rebstock M.	2011	5-OH-ASTP metabolite of florasulam (X12251401): growth inhibition test with the	N	N	-	Dow Agro Science

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			unicellular green alga, *Pseudokirchneriella subcapitata.* GLP, unpublished				
KCP 10.2	Rebstock M.	2011	ASTP metabolite of florasulam (X516274): growth inhibition test with the unicellular green alga, *Pseudokirchneriella subcapitata.* GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Rebstock M.	2011	DFP-ASTCA metabolite of florasulam (X12239339): growth inhibition test with the freshwater aquatic plant, duckweed, *Lemna gibba* GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Rebstock M.	2011	5-OH-ASTP metabolite of florasulam (X12251401): growth inhibition test with the freshwater aquatic plant, duckweed, *Lemna gibba* GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Rebstock M.	2011	TSA metabolite of florasulam (X634074): growth inhibition test with the freshwater aquatic plant, duckweed, *Lemna gibba* GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Rebstock M.	2011	ASTP metabolite of florasulam (X516274): growth inhibition test with the freshwater aquatic plant, duckweed, *Lemna gibba* GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Rebstock M.	2011	DFP-ASTCA metabolite of florasulam (X12239339): growth inhibition test with the unicellular green alga, *Pseudokirchneriella subcapitata* GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.2	Rebstock M.	2011	TSA metabolite of florasulam (X634074): growth inhibition test with the unicellular	N	N	-	Dow Agro Science

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			green alga, *Pseudokirchneriella subcapitata*. GLP, unpublished				
KCP 10.2	Shillabeer, kent & Smith	1997	Chronic toxicity of mesotrione to *Pseudo-kirchneriella subcapitata* GLP, not published	N	N	-	Syngenta
KCP 10.2	Smith, Magor & Shillabeer	1998c	Chronic toxicity of AMBA (99% purity) to *Pseudokirchneriella subcapitata* GLP, not published	N	N	-	Syngenta
KCP 10.2	Smyth *et al.*	1997c	Chronic toxicity of MNBA (97.1% purity) to *Pseudokirchneriella subcapitata* GLP, not published	N	N	-	Syngenta
KCP 10.2	Smyth *et al.*	1997d	Chronic toxicity of mesotrione to *Lemna gibba* GLP, not published	N	N	-	Syngenta
KCP 10.2	Taylor S., Taylor J.	2013b	ZA1296 - Statistical Re-analysis: Chronic toxicity to fathead minnow (Pimephales pro-melas) embryos and larvae Syngenta Cambridge Environmental Assessments, Unit-ed Kingdom, CEA.1043 Not GLP, not published Syngenta File No ZA1296_10151	Y	N	-	Syngenta
KCP 10.2	Ward T.J. et al.	1995	XDE-570: Acute toxicity to the grass shrimp, *Palaemonetes pungo* GLP, unpublished	N	N	-	Dow Agro Science
KCP 10.3.1	Beech, P.	1996	A Determination of the Oral LD50s for XDE 570 against the Honey Bee, Apis mel-lifera Agrochemical Evaluation Unit, Depart-ment of Biology, The University, Southamp-ton, UK DOW-96-3 GHE-P-6705 GLP/GEP (Y/N) Y Published (Y/N) N	N	N	-	Dow Agro Science
KCP 10.3.1	Jackson, D. & Gough, H.J.	1995	ZA 1296: Acute Contact and Oral Toxicity to the Honey Bees (Apis mellifera) of Technical Material	N	N	-	Syngenta

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			GLP, not published				
KCP 10.3.1	Palmer, SJ	1994	XDE-570: An Acute Contact Study with the Honey Bee Wildlife International Ltd, Easton, Maryland, USA 103-407 DECO-ES-2819 GLP/GEP (Y/N) Y Published (Y/N) N	N	N	-	Dow Agro Science
KCP 10.3.2	Austin, H.M.	1997	A Laboratory Study to Evaluate the Effects of XDE-570 on the Predatory Mite, Typhlodromus pyri Ecotox Limited, Tavistock, Devon, UK ER-96-31 GHE-P-6706 GLP/GEP (Y/N) Y Published (Y/N) N	N	N	-	Dow Agro Science
KCP 10.3.2	Austin, H.M.	1997	A Laboratory Study to Evaluate the Effects of XDE-570 on the Parasitic Wasp, Aphidius rhopalosiphi Ecotox Limited, Tavistock, Devon, UK ER-96-34 GHE-P-6707 GLP/GEP (Y/N) Y Published (Y/N) N	N	N	-	Dow Agro Science
KCP 10.4	Bembridge, J.D. & Jackson, D.	1996	ZA 1296: Toxicity of Technical Material to the Earthworm Eisenia fetida in an Artificial Soil Test. Zeneca Agrochemicals Report No: RJ2225B. DP 59893.	N	N	-	Syngenta
KCP 10.4	Friedrich S,	2013a	R169649 – Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil with 5 % Peat, Report Number 13 10 48 086 S. BioChem agrar Labor für biologische und chemische Analytik GmbH, Kupferstraße 6 04827 Gerichshain, Germany (Syngenta file No. CA3511_10002).	N	N	-	Syngenta
KCP 10.4	Friedrich S.	2013b	R44276 – Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil with 5% Peat, Report Number 13 10 48 111 S.	N	N	-	Syngenta

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			BioChem agrar Labor für biologische und chemische Analytik GmbH, Kupferstraße 6, 04827 Gerichshain, Germany. (Syngenta file No. R044276_10002).				
KCP 10.4	Lührs, U.	2008b	Effects of ASTCA metabolite of florasulam on reproduction and growth of earthworms Eisenia fetida in artificial soil Institut fiir Biologische Analytik und Consulting IBACON GmbH DAS Report No.: 080038 (Accession Number) 2001599 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	-	Dow Agro Science
KCP 10.4	Witte, B.	2010b	Effects of 5-hydroxy-florasulam on reproduction and growth of earthworms Eisenia fetida in artificial soil Institut fiir Biologische Analytik und Consulting IBACON GmbH DAS Report No.: 101340 (Accession Number) 2006605 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	-	Dow Agro Science
KCP 10.4	Witte, B.	2011a	Effects of DFP-ASTCA metabolite of florasulam on reproduction and growth of earthworms Eisenia fetida in artificial soil Institut fiir Biologische Analytik und Consulting IBACON GmbH DAS Report No.: 101341 (Accession Number) 2009374 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	-	Dow Agro Science
KCP 10.4	Witte, B.	2011b	Effects of TSA metabolite of florasulam on reproduction and growth of earthworms Eisenia fetida in artificial soil Institut fiir	N	N	-	Dow Agro Science

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro-tection is claimed	Owner
			Biologische Analytik und Consulting IBACON GmbH DAS Report No.: 110132 (Accession Number) 2009730 GLP/GEP (Y/N): Y Published (Y/N): N				
KCP 10.5	Feil, N.	2008	Effects of ASTCA metabolite of florasulam on the activity of the soil microflora in the laboratory. Institut fiir Biologische Analytik und Consulting IBACON GmbH DAS Report No.: 080039 (Accession Number) 2000205 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	-	Dow Agro Science
KCP 10.5	Feil, N.	2010	Effects of 5-hydroxy-florasulam on the activity of the soil microflora in the laboratory Institut fiir Biologische Analytik und Consulting IBACON GmbH DAS Report No.: 101342 (Accession NNumber) 2007411 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	-	Dow Agro Science
KCP 10.5	Feil, N.	2011a	Effects of DFP-ASTCA metabolite of florasulam on the activity of the soil microflora in the laboratory. Institut fiir Biologische Analytik und Consulting IBACON GmbH DAS Report No.: 101343 (Accession Number) 2009901 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	-	Dow Agro Science
KCP 10.5	Feil, N.	2011b	Effects of TSA metabolite of florasulam on the activity of the soil microflora in the laboratory	N	N	-	Dow Agro Science

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			Institut fiir Biologische Analytik und Consulting IBACON GmbH DAS Report No.: 110143 (Accession Number) 2010747 GLP/GEP (Y/N): Y Published (Y/N): N				
KCP 10.5	Schulz L,	2013b	R169649 and R44276 – Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests), Report Number 12 10 48 045 C/N. BioChem agrar, Labor für biologische und chemische Analytik GmbH, Kupferstraâe 6, 04827 Gerichshain, Germany (Syngenta file No. CA3511_10000).	N	N	-	Syngenta
IIA 6.12.1 (Annex IIA 5.8.1)	Mecchi M.S.	2008	*Salmonella Escherichia coli*/Mammalian-Microsome Reverse Mutation Assay Preincubation Method with a Confirmatory Assay with ASTCA Metabolite of Florasulam Covance Laboratories Inc DAS Report No.: 071120 (Accession Number) 257169 GLP/GEP Published	N	N	-	Dow Agro Science
IIA 6.12.2 (Annex IIA 5.8.2)	Schisler,M.R. and Geter, D.R.	2008	Evaluation of Florasulam ASTCA Metabolite in the Chinese Hamster ovary Ell/hypoxanthine-guanine-phosphoribosyl Transferase (cho/hgprt) Forward Mutation Assay Toxicology & Environmental Research and Consulting DAS Report No.: 071133 (Accession Number) 257174 GLP/GEP, Published	N	N	-	Dow Agro Science
IIA 6.12.3 (Annex IIA 5.8.3)	Schisler, M.R , Kleinert, K.M. and D. R. Geter, D.R	2008	Evaluation of Florasulam ASTCA Metabolite in an *in vitro* Chromosomal Aberration Assay Utilizing Rat Lymphocytes Toxicology & Environmental Research and Consulting DAS Report No.: 071132 (Accession Number)	N	N	-	Dow Agro Science

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data pro-tection is claimed	Owner
			257142 GLP/GEP, Published				
IIA 6.12.4 (Annex IIA 5.8.4)	Nagane, R.M.	2011a	Bacterial Reverse Mutation Test of TSA Metabolite of Florasulam using *Salmonella typhimurium* Jai Research Foundation DAS Report No.: 110432 (Accession Number) 2010127 GLP/GEP, Published	N	N	-	Dow Agro Science
IIA 6.12.5 (Annex IIA 5.8.5)	Nagane, R.M.	2011b	*In vitro* Mammalian Cell Gene Forward Mutation Test at the hgprt Locus of the Chinese Hamster Ovary (CHO)-K1 Cell Line using TSA metabolite of florasulam Jai Research Foundation DAS Report No.: 110430 (Accession Number) 2010107 GLP/GEP (Y/N): Y Published (Y/N): N	N	N	-	Dow Agro Science
IIA 6.12.6 (Annex IIA 5.8.6)	Nagane, R.M.	2011c	*In vitro* Mammalian Chromosome Aberration Test of TSA Metabolite of Florasulam in Human Peripheral Blood Lymphocytes Jai Research Foundation DAS Report No.: 110431 (Accession Number) 2010112 GLP/GEP, Published	N	N	-	Dow Agro Science

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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

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

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