

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: CHR/H/IZOXACYP 250 SC

Product name(s):

Metida Plus 250 SC

Taizza Plus 250 SC

Chemical active substance:

Isoxaflutole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: Innvigo Sp. z o. o.

Submission date: April 2022, November 2022, August 2025,
September 2025

MS Finalisation date: January 2023, August 2023, October 2023,
April 2024; July 2025; October 2025; February 2026

Version history

When	What
January 2023	ZRMs evaluated dRR submitted by Applicant
August 2023	Final version of RR after commenting period.
October 2023	ZRMS corrections in the Conclusions and the list of of data considered for national authorization
April 2024	zRMS assessment of 2-years stability data
July 2025	Risk mitigation included by zRMS
August 2025	Applicant update
September 2025	Applicant update
October 2025	Assessment of the new analytical methods for residues
February 2026	The final Registration Report after the reporting period

Table of Contents

1	Details of the application	5
1.1	Application background	5
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	6
1.4	Data protection claims	6
2	Details of the authorization decision	6
2.1	Product identity	6
2.2	Conclusion	7
2.3	Substances of concern for national monitoring	8
2.4	Classification and labelling	8
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	8
2.4.2	Standard phrases under Regulation (EU) No 547/2011	9
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	9
2.5	Risk management	9
2.5.1	Restrictions linked to the PPP	9
2.5.2	Specific restrictions linked to the intended uses	10
2.6	Intended uses (only NATIONAL GAP)	11
3	Background of authorization decision and risk management	13
3.1	Physical and chemical properties (Part B, Section 2)	13
3.2	Efficacy (Part B, Section 3)	13
3.3	Efficacy data	13
3.3.1	Information on the occurrence or possible occurrence of the development of resistance	18
3.3.2	Adverse effects on treated crops	19
3.3.3	Observations on other undesirable or unintended side-effects	19
3.4	Methods of analysis (Part B, Section 5)	19
3.4.1	Analytical method for the formulation	20
3.4.2	Analytical methods for residues	22
3.5	Mammalian toxicology (Part B, Section 6)	22
3.6	Residues and consumer exposure (Part B, Section 7)	23
3.6.1	Consumer exposure	24
3.7	Environmental fate and behaviour (Part B, Section 8)	25
3.7.1	Predicted environmental concentrations in soil (PEC_{soil})	25
3.7.2	Predicted environmental concentrations in groundwater (PEC_{gw})	25
3.7.3	Predicted environmental concentrations in surface water/sediment ($PEC_{sw/sed}$)	26
3.7.4	Ecotoxicology (Part B, Section 9)	26
3.7.4.1	Effects on terrestrial vertebrates	26
3.7.4.2	Effects on aquatic species	26
3.7.4.3	Effects on bees	26
3.7.4.4	Effects on other arthropod species other than bees	26
3.7.4.5	Effects on soil organisms	26

3.7.4.6	Effects on non-target terrestrial plants	27
3.7.4.7	Effects on other terrestrial organisms (Flora and Fauna).....	27
3.8	Relevance of metabolites (Part B, Section 10)	27
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	27
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization	27
Appendix 1	Copy of the product authorization	27
Appendix 2	Copy of the product label	29
Appendix 3	Letter of Access	39
Appendix 4	Lists of data considered for national authorization.....	40

PART A

RISK MANAGEMENT

New and additional information are highlighted in green

New and additional information added in 09/2025 are highlighted in yellow

The changes only concern the Analytical Methods section.

1 Details of the application

This document describes the acceptable use conditions required for zonal registration of CHR/H/IZOXACYP 250 SC (Metida Plus 250 SC, Taizza Plus 250 SC) containing Isoxaflutole in POLAND (zRMS).

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

This document describes the specific conditions of use and labelling required for the registration of (Metida Plus 250 SC, Taizza Plus 250 SC), product code CHR/H/IZOXACYP 250 SC.

1.1 Application background

This application was finalized by Innvigo Sp. z o.o in March 2022. Innvigo Sp. z o.o. is a company located at Aleje Jerozolimskie 178, 02-486, Warsaw, Poland, and registered in the Polish National Court Registry of entrepreneurs (KRS), with the number 0000540684.

The application is for the approval of CHR/H/IZOXACYP a suspension concentrate type formulation (SC) containing 250 g/L of Isoxaflutole for use as a herbicide for controls a broad-spectrum of dicots and monocots weeds in maize.

It is applied by spray at BBCH 00 to 09 (pre-emergence) and BBCH 11 to 13 (post-emergence) (details GAP table B0 Section)

To obtain authorisation the product CHR/H/IZOXACYP must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

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

1.2 Letters of Access

Confidential information - data are provided separately (Part C).

1.3 Justification for submission of tests and studies

In accordance with Art. 33 (3), the submitted studies and presented in Appendix 4, are relevant and necessary to obtain the first authorisation the product CHR/H/IZOXACYP in Poland.

1.4 Data protection claims

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

2 Details of the authorization decision

2.1 Product identity

Product code	CHR/H/IZOXACYP 250 SC
Product name in MS	Metida Plus 250 SC, Taizza Plus 250 SC
Authorization number	N/D
Function	herbicide
Applicant	Innvigo Sp. z o. o.
Active substance(s) (incl. content)	Isoxaflutole; 250 g/L
Formulation type	Suspension concentrate (SC)
Packaging	HDPE: 200 mL HDPE bottles 250 mL HDPE bottles 500 mL HDPE bottles 510 mL HDPE jar 564 mL HDPE bottle 600 mL HDPE bottle 800 mL HDPE bottle 800 mL HDPE jar 1000 mL HDPE bottle 1200 mL HDPE bottle 2000 mL HDPE bottle 2000 mL HDPE jar 3000 mL HDPE container 4000 mL HDPE cannister 5000 mL HDPE cannister 5000 mL HDPE container 5850 mL HDPE container 6000 mL HDPE cannister 10000 mL HDPE containers 11220 mL HDPE containers 20000 mL HDPE containers 22000 mL HDPE containers HDPE/PA 275 mL HDPE/PA bottle 500 mL HDPE/PA bottles

	574 mL HDPE/PA bottles 1000 mL HDPE/PA bottles HDPE/PA COEX 323 mL HDPE/PA COEX bottle 550 mL HDPE/PA COEX bottles 1000 mL HDPE/PA COEX bottles 1100 mL HDPE/PA COEX bottles 5000 mL HDPE/PA COEX bottle 5000 mL HDPE/PA COEX cannister 5500 mL HDPE/PA COEX bottle 5850 mL HDPE/PA COEX container 10000 mL HDPE/PA COEX containers HDPE/F 312 mL HDPE/F bottles 318 mL HDPE/F bottles 570 mL HDPE/F bottles 575 mL HDPE/F bottles 580 mL HDPE/F bottles 585 mL HDPE/F bottles 1150 mL HDPE/F bottles 1160 mL HDPE/F bottles 1185 mL HDPE/F bottles 1200 mL HDPE/F bottle 5880 mL HDPE/F cannisters 5950 ml HDPE/F bottles 5950 ml HDPE/F cannister 10000 mL HDPE/F cannister HDPE/EvOH 250 mL HDPE/EvOH bottle 310 mL HDPE/EvOH bottle 500 mL HDPE/EvOH bottles 580 mL HDPE/EvOH bottle 1000 mL HDPE/EvOH bottle 1200 mL HDPE/EvOH bottle 5000 mL HDPE/EvOH container 5650 mL HDPE/EvOH cannister 10000 mL HDPE/EvOH container 20000 mL HDPE/EvOH container
Coformulants of concern for national authorizations	N/A
Restrictions related to identiy	N/A
Mandatory tank mixtures	N/A
Recommended tank mixtures	N/A

2.2 Conclusion

Analytical Methods:

Method Validation for Determination of Isoxaflutole and Metabolites in Water, Independent Laboratory Validation for Determination of Isoxaflutole and Metabolites in Drinking Water and Method Validation for Determination of Isoxaflutole and its Metabolite RPA 202248 in Body Fluids and Tissues were provided. Methods are accepted. The data gap has been filled.

2.3 Substances of concern for national monitoring

This point is not relevant for authorisation of CHR/H/IZOXACYP.


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:	Skin Sens. 1A, Repr. 2, Aquatic Acute 1, Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	
Signal word:	Warning
Hazard statement(s):	H317: May cause an allergic skin reaction. H361d: Suspected of damaging the unborn child. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	<p>WARNING SECTION OF THE LABEL (first page)</p> <p>P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352 – IF ON SKIN: Wash with plenty of water with soap. P308+P313 – IF exposed or concerned: Get medical advice/attention. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P391 – Collect spillage.</p> <p>Other section of the label: P501 - Dispose of contents/container to ...</p> <p>And P280 as follows:</p> <p>OPERATOR: „Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.” “Wear protective gloves, eye/face protection and protective clothing during mixing and loading and application.”</p> <p>WORKER: “Stosować rękawice ochronne oraz odzież ochronną”. “Wear protective gloves and protective clothing”</p>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	

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).
e.g.SPe3	To protect aquatic organisms/non-target plants/non-target arthropods/insects respect an unsprayed buffer zone of (distance to be specified) to non-agricultural land/surface water bodies.
	W celu ochrony wód gruntowych/nie stosować tego lub żadnego innego produktu zawierającego isoksafłutol częściej niż raz na trzy lata To protect groundwater, do not use this or any other product containing isoxaflutole more than once every three years.

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

	N/A
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2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
N/A	With gloves and workwear during mixing and loading
Worker protection:	
N/A	With workwear
Integrated pest management (IPM)/sustainable use:	
N/A	The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
N/A	Aquatic species: - 20 meter vegetative and 20 meters no-spray buffer zone NTP: - 5 m buffer zone - 1 m buffer zone and use of 90% drift reducing nozzles
Other specific restrictions	
N/A	No other specific restrictions

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

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

2.5.2 Specific restrictions linked to the intended uses

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

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
N.A	The instructions for use must include a summary of weeds which can be controlled well, less well and insufficiently by the product, as well as a list of species and/or varieties showing which crops are tolerant of the intended application rate and which are not.	use number from GAP table in 2.6
Environmental protection:		Relevant for use no.
respective code if available	In order to protect non-target plants and other measure is necessary the appointment of a protection zone with a width of 5 m of land not used for agricultural or 1 m and the use of 90% drift reducing nozzles To protect groundwater/soil organisms do not apply this or any other product containing (identify active substance or class of substances, as appropriate) more than (time period or frequency to be specified).	use number from GAP table in 2.6

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Metida Plus 250 SC, Taizza Plus 250 SC / CHR/H/IZOXACYP 250 SC Formulation type: SC ^(a, b)

Active substance 1: isoxaflutole Conc. of as 1: 250 g/L ^(c)

Active substance 2: N/D Conc. of as 2: N/D

Safener: cyprosulfamide Conc. of safener: 250 g/L ^(c)

Synergist: N/D Conc. of synergist: N/D

Applicant: Innvigo Sp. z o. o. Professional use: ☒

Zone(s): central ^(d) Non professional use: ☐

Verified by MS: no

GAP rev. , date: 2020-12-16

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, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal 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	Mono- and dicots weeds	Spray	Pre-emergence BBCH 00-09	a)1 b)1	N/A	a) 0.28 L prod- uct/ha b) 0.28 L prod- uct/ha	a) 70 g as/ha b) 70 g as/ha	200- 300	N/A	Efficacy section: only maize is ac- cepted.
2	PL	Maize,	F	Mono- and dicots weeds	Spray	Post-emergence BBCH 11-13	a)1 b)1	N/A	a) 0.30 L prod- uct/ha b) 0.30 L prod- uct/ha	a) 75 g as/ha b) 75 g as/ha	200- 300	N/A	Efficacy section: only maize is ac- cepted.

Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph 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 light-brown, with a delicate odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a auto-ignition temperature of 610°C. In aqueous solution, it has a pH value around 4.3 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 after 2 years of storage indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a herbicide formulation.

The intended concentration of use is 0.1% to 0.2%.

3.2 Efficacy (Part B, Section 3)

The 30 trials (preemergence application 14 trials, postemergence application 16 trials) have been carried out in 2020, 2021 and 2022 in the North-East EPPO zone within the Central registration zone to evaluate the efficacy of applied at the proposed label rate of 70 g a.s./ha isoxaflutole (preemergence application) and 75 g a.s./ha (postemergence application) for the weed control in maize.

Tested herbicide was applied at the growth stage in maize:

Preemergence BBCH 00-09

and postemergence BBCH 11-13.

The product CHR/H/IZOXACYP 250 SC has been used in maize at the following rates of:

0.16, 0.20, 0.24 and 0.28 L/ha – preemergence,

0.20, 0.25, 0.3, 0.35 and 0.4 L/ha – postemergence.

Adengo 315 SC was used as a reference product in maize.

3.3 Efficacy data

The submitted efficacy data (reports from 30 field trials) and additional information fulfill requirements and conditions determined in the following EPPO guidelines:

- PP 1/135 (3) Phytotoxicity assessment

- PP 1/152 (3) Design and analysis of efficacy evaluation trials

- PP 1/181 (3) Conduct and reporting of efficacy evaluation trials including good experimental practice

They were carried out on the field in the conditions of natural agrofag infestation. The efficacy trials were concluded according to the EPPO standards:

- PP 1/50(3) Weeds in maize

- PP 1/50(4) Weeds in maize

The studies fulfill also requirements of the Commission Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products.

The formulation of CHR/H/IZOXACYP 250 SC is suspension concentrate (SC) and it comprises active substance 250 g/L isoxaflutole. The applicant submitted 30 reports in total (14 trials – preemergence application and 16 trials – postemergence application) showing the results in research into product efficacy carried out in 2020 and 2021 in maize.

The obtained data in performed trials show that CHR/H/IZOXACYP 250 SC provides benefits against the most important weeds in maize as shown in the table below.

The following table describes the effectiveness of weeds:

S (Susceptible)	> 85% (within each trial the average must be higher than 85%)
MS (Moderately Susceptible)	70 – 85%
MT (Moderately Tolerant)	60 – 70%
T (Tolerant)	< 60%

The following table shows the average sensitivity of weeds in maize:

MAIZE – PREEMERGENCE APPLICATION

Product code (L, kg/ha)	EPPO code	Scientific name	DA-A	Pest stage	Average	Efficacy
CHR/H/IZOXACYP 250 SC 0.16 L/ha	CHEAL	<i>Chenopodium album</i>	22-29 DA-A	BBCH 00	69.72	MT
	ANTAR	<i>Anthemis arvensis</i>	22-28 DA-A	BBCH 00	73.02	MS
	POLPE	<i>Polygonum persicaria</i>	28-39 DA-A	BBCH 00	75.52	MS
	THLAR	<i>Thlaspi arvense</i>	22-28 DA-A	BBCH 00	73.18	MS
	VIOAR	<i>Viola arvensis</i>	22-29 DA-A	BBCH 00	67.30	MT
	ECHCG	<i>Echinochloa crus-galli</i>	22-29 DA-A	BBCH 00	72.41	MS
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 00	76.48	MS
	MATIN	<i>Tripleurospermum inodorum</i>	22-28 DA-A	BBCH 00	61.95	MT
	STEME	<i>Stellaria media</i>	22-28 DA-A	BBCH 00	73.15	MS
	BRSNW	<i>Brassica napus (self-sown plant)</i>	27-28 DA-A	BBCH 00	58.11	T
	AMARE	<i>Amaranthus retroflexus</i>	22-28 DA-A	BBCH 00	68.44	MT
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 00	78.23	MS
CHR/H/IZOXACYP 250 SC 0.20 L/ha	CHEAL	<i>Chenopodium album</i>	22-29 DA-A	BBCH 00	76.12	MS
	ANTAR	<i>Anthemis arvensis</i>	22-28 DA-A	BBCH 00	78.37	MS
	POLPE	<i>Polygonum persicaria</i>	28-39 DA-A	BBCH 00	82.20	MS
	THLAR	<i>Thlaspi arvense</i>	22-28 DA-A	BBCH 00	76.77	MS
	VIOAR	<i>Viola arvensis</i>	22-29 DA-A	BBCH 00	71.50	MS
	ECHCG	<i>Echinochloa crus-galli</i>	22-29 DA-A	BBCH 00	75.10	MS
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 00	81.95	MS
	MATIN	<i>Tripleurospermum inodorum</i>	22-28 DA-A	BBCH 00	70.26	MS
	STEME	<i>Stellaria media</i>	22-28 DA-A	BBCH 00	78.37	MS
	BRSNW	<i>Brassica napus (self-sown plant)</i>	27-28 DA-A	BBCH 00	67.70	MT
	AMARE	<i>Amaranthus retroflexus</i>	22-28 DA-A	BBCH 00	75.86	MS
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 00	82.07	MS
CHR/H/IZOXACYP 250 SC 0.24 L/ha	CHEAL	<i>Chenopodium album</i>	22-29 DA-A	BBCH 00	83.50	MS
	ANTAR	<i>Anthemis arvensis</i>	22-28 DA-A	BBCH 00	83.15	MS
	POLPE	<i>Polygonum persicaria</i>	28-39 DA-A	BBCH 00	87.65	S
	THLAR	<i>Thlaspi arvense</i>	22-28 DA-A	BBCH 00	81.90	MS
	VIOAR	<i>Viola arvensis</i>	22-29 DA-A	BBCH 00	76.78	MS
	ECHCG	<i>Echinochloa crus-galli</i>	22-29 DA-A	BBCH 00	81.19	MS
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 00	88.43	S

	MATIN	<i>Tripleurospermum inodorum</i>	22-28 DA-A	BBCH 00	81.83	MS
	STEME	<i>Stellaria media</i>	22-28 DA-A	BBCH 00	86.22	S
	BRSNW	<i>Brassica napus (self-sown plant)</i>	27-28 DA-A	BBCH 00	73.88	MS
	AMARE	<i>Amaranthus retroflexus</i>	22-28 DA-A	BBCH 00	84.84	MS
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 00	86.23	S
CHR/H/IZOXACYP 250 SC 0.28 L/ha	CHEAL	<i>Chenopodium album</i>	22-29 DA-A	BBCH 00	89.43	S
	ANTAR	<i>Anthemis arvensis</i>	22-28 DA-A	BBCH 00	87.73	S
	POLPE	<i>Polygonum persicaria</i>	28-39 DA-A	BBCH 00	92.65	S
	THLAR	<i>Thlaspi arvense</i>	22-28 DA-A	BBCH 00	87.13	S
	VIOAR	<i>Viola arvensis</i>	22-29 DA-A	BBCH 00	83.81	MS
	ECHCG	<i>Echinochloa crus-galli</i>	22-29 DA-A	BBCH 00	86.69	S
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 00	94.18	S
	MATIN	<i>Tripleurospermum inodorum</i>	22-28 DA-A	BBCH 00	86.53	S
	STEME	<i>Stellaria media</i>	22-28 DA-A	BBCH 00	91.20	S
	BRSNW	<i>Brassica napus (self-sown plant)</i>	27-28 DA-A	BBCH 00	81.86	MS
	AMARE	<i>Amaranthus retroflexus</i>	22-28 DA-A	BBCH 00	91.72	S
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 00	90.93	S
Adengo 315 SC 0.33 L/ha	CHEAL	<i>Chenopodium album</i>	22-29 DA-A	BBCH 00	91.63	S
	ANTAR	<i>Anthemis arvensis</i>	22-28 DA-A	BBCH 00	91.53	S
	POLPE	<i>Polygonum persicaria</i>	28-39 DA-A	BBCH 00	98.93	S
	THLAR	<i>Thlaspi arvense</i>	22-28 DA-A	BBCH 00	92.95	S
	VIOAR	<i>Viola arvensis</i>	22-29 DA-A	BBCH 00	81.30	MS
	ECHCG	<i>Echinochloa crus-galli</i>	22-29 DA-A	BBCH 00	89.99	S
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 00	95.88	S
	MATIN	<i>Tripleurospermum inodorum</i>	22-28 DA-A	BBCH 00	76.28	MS
	STEME	<i>Stellaria media</i>	22-28 DA-A	BBCH 00	84.96	MS
	BRSNW	<i>Brassica napus (self-sown plant)</i>	27-28 DA-A	BBCH 00	87.00	S
	AMARE	<i>Amaranthus retroflexus</i>	22-28 DA-A	BBCH 00	87.12	S
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 00	86.93	S

MAIZE – POSTEMERGENCE APPLICATION

Product code (L, kg/ha)	EPPO code	Scientific name	DA-A	Pest stage	Average	Efficacy
CHR/H/IZO XACYP 250 SC 0.20 L/ha	CHEAL	<i>Chenopodium album</i>	25-28 DA-A	BBCH 10-16	64.96	MT
	POLCO	<i>Polygonum convolvulus</i>	25-28 DA-A	BBCH 10-16	7.92	T
	ANTAR	<i>Anthemis arvensis</i>	26-28 DA-A	BBCH 10-14	72.40	MS
	POLPE	<i>Polygonum persicaria</i>	25-28 DA-A	BBCH 10-14	70.01	MS
	THLAR	<i>Thlaspi arvense</i>	25-28 DA-A	BBCH 10-16	73.52	MS
	VIOAR	<i>Viola arvensis</i>	25-28 DA-A	BBCH 10-21	83.92	MS
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 10-14	68.70	MT
	ECHCG	<i>Echinochloa crus-galli</i>	25-28 DA-A	BBCH 10-14	51.56	T
	SINAR	<i>Sinapsis arvensis</i>	27-28 DA-A	BBCH 10-14	71.50	MS
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 10-14	82.50	MS
	MATIN	<i>Tripleurospermum inodorum</i>	27-28 DA-A	BBCH 10-30	79.86	MS
	VERHE	<i>Veronica hederifolia</i>	25-28 DA-A	BBCH 10-14	58.26	T
	STEME	<i>Stellaria media</i>	25-28 DA-A	BBCH 10-31	91.00	S

	BRSNW	<i>Brassica napus</i> (self-sown plant)	25-28 DA-A	BBCH 10-16	55.02	T
	AMARE	<i>Amaranthus retroflexus</i>	26-28 DA-A	BBCH 10-16	63.55	MT
CHR/H/IZO XACYP 250 SC 0.25 L/ha	CHEAL	<i>Chenopodium album</i>	25-28 DA-A	BBCH 10-16	76.21	MS
	POLCO	<i>Polygonum convolvulus</i>	25-28 DA-A	BBCH 10-16	23.24	T
	ANTAR	<i>Anthemis arvensis</i>	26-28 DA-A	BBCH 10-14	84.55	MS
	POLPE	<i>Polygonum persicaria</i>	25-28 DA-A	BBCH 10-14	82.91	MS
	THLAR	<i>Thlaspi arvense</i>	25-28 DA-A	BBCH 10-16	90.43	S
	VIOAR	<i>Viola arvensis</i>	25-28 DA-A	BBCH 10-21	89.51	S
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 10-14	81.13	MS
	ECHCG	<i>Echinochloa crus-galli</i>	25-28 DA-A	BBCH 10-14	62.97	MT
	SINAR	<i>Sinapsis arvensis</i>	27-28 DA-A	BBCH 10-14	84.67	MS
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 10-14	90.02	S
	MATIN	<i>Tripleurospermum inodorum</i>	27-28 DA-A	BBCH 10-30	87.97	S
	VERHE	<i>Veronica hederifolia</i>	25-28 DA-A	BBCH 10-14	69.85	MT
	STEME	<i>Stellaria media</i>	25-28 DA-A	BBCH 10-31	96.25	S
	BRSNW	<i>Brassica napus</i> (self-sown plant)	25-28 DA-A	BBCH 10-16	73.60	MS
	AMARE	<i>Amaranthus retroflexus</i>	26-28 DA-A	BBCH 10-16	76.77	MS
CHR/H/IZO XACYP 250 SC 0.30 L/ha	CHEAL	<i>Chenopodium album</i>	25-28 DA-A	BBCH 10-16	85.42	S
	POLCO	<i>Polygonum convolvulus</i>	25-28 DA-A	BBCH 10-16	28.85	T
	ANTAR	<i>Anthemis arvensis</i>	26-28 DA-A	BBCH 10-14	89.93	S
	POLPE	<i>Polygonum persicaria</i>	25-28 DA-A	BBCH 10-14	95.14	S
	THLAR	<i>Thlaspi arvense</i>	25-28 DA-A	BBCH 10-16	98.30	S
	VIOAR	<i>Viola arvensis</i>	25-28 DA-A	BBCH 10-21	93.44	S
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 10-14	87.93	S
	ECHCG	<i>Echinochloa crus-galli</i>	25-28 DA-A	BBCH 10-14	71.13	MS
	SINAR	<i>Sinapsis arvensis</i>	27-28 DA-A	BBCH 10-14	96.25	S
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 10-14	99.05	S
	MATIN	<i>Tripleurospermum inodorum</i>	27-28 DA-A	BBCH 10-30	95.97	S
	VERHE	<i>Veronica hederifolia</i>	25-28 DA-A	BBCH 10-14	78.38	MS
	STEME	<i>Stellaria media</i>	25-28 DA-A	BBCH 10-31	97.72	S
	BRSNW	<i>Brassica napus</i> (self-sown plant)	25-28 DA-A	BBCH 10-16	79.98	MS
	AMARE	<i>Amaranthus retroflexus</i>	26-28 DA-A	BBCH 10-16	91.73	S
CHR/H/IZO XACYP 250 SC 0.35 L/ha	CHEAL	<i>Chenopodium album</i>	25-28 DA-A	BBCH 10-16	89.93	S
	POLCO	<i>Polygonum convolvulus</i>	25-28 DA-A	BBCH 10-16	35.13	T
	ANTAR	<i>Anthemis arvensis</i>	26-28 DA-A	BBCH 10-14	93.52	S
	POLPE	<i>Polygonum persicaria</i>	25-28 DA-A	BBCH 10-14	99.38	S
	THLAR	<i>Thlaspi arvense</i>	25-28 DA-A	BBCH 10-16	99.58	S
	VIOAR	<i>Viola arvensis</i>	25-28 DA-A	BBCH 10-21	96.87	S
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 10-14	94.60	S
	ECHCG	<i>Echinochloa crus-galli</i>	25-28 DA-A	BBCH 10-14	83.98	MS
	SINAR	<i>Sinapsis arvensis</i>	27-28 DA-A	BBCH 10-14	97.58	S
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 10-14	100.00	S
	MATIN	<i>Tripleurospermum inodorum</i>	27-28 DA-A	BBCH 10-30	97.88	S
	VERHE	<i>Veronica hederifolia</i>	25-28 DA-A	BBCH 10-14	87.85	S
	STEME	<i>Stellaria media</i>	25-28 DA-A	BBCH 10-31	99.08	S
	BRSNW	<i>Brassica napus</i> (self-sown plant)	25-28 DA-A	BBCH 10-16	89.22	S
	AMARE	<i>Amaranthus retroflexus</i>	26-28 DA-A	BBCH 10-16	94.72	S
CHR/H/IZO XACYP 250	CHEAL	<i>Chenopodium album</i>	25-28 DA-A	BBCH 10-16	97.25	S
	POLCO	<i>Polygonum convolvulus</i>	25-28 DA-A	BBCH 10-16	58.50	T

SC 0.40 L/ha	ANTAR	<i>Anthemis arvensis</i>	26-28 DA-A	BBCH 10-14	100.00	S
	POLPE	<i>Polygonum persicaria</i>	25-28 DA-A	BBCH 10-14	100.00	S
	THLAR	<i>Thlaspi arvense</i>	25-28 DA-A	BBCH 10-16	100.00	S
	VIOAR	<i>Viola arvensis</i>	25-28 DA-A	BBCH 10-21	97.90	S
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 10-14	100.00	S
	ECHCG	<i>Echinochloa crus-galli</i>	25-28 DA-A	BBCH 10-14	97.40	S
	SINAR	<i>Sinapsis arvensis</i>	27-28 DA-A	BBCH 10-14	100.00	S
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 10-14	100.00	S
	MATIN	<i>Tripleurospermum inodorum</i>	27-28 DA-A	BBCH 10-30	100.00	S
	VERHE	<i>Veronica hederifolia</i>	25-28 DA-A	BBCH 10-14	97.00	S
	STEME	<i>Stellaria media</i>	25-28 DA-A	BBCH 10-31	100.00	S
	BRSNW	<i>Brassica napus</i> (self-sown plant)	25-28 DA-A	BBCH 10-16	100.00	S
	AMARE	<i>Amaranthus retroflexus</i>	26-28 DA-A	BBCH 10-16	-	-
Adengo 315 SC 0.33 L/ha	CHEAL	<i>Chenopodium album</i>	25-28 DA-A	BBCH 10-16	93.60	S
	POLCO	<i>Polygonum convolvulus</i>	25-28 DA-A	BBCH 10-16	97.31	S
	ANTAR	<i>Anthemis arvensis</i>	26-28 DA-A	BBCH 10-14	98.97	S
	POLPE	<i>Polygonum persicaria</i>	25-28 DA-A	BBCH 10-14	99.31	S
	THLAR	<i>Thlaspi arvense</i>	25-28 DA-A	BBCH 10-16	100.00	S
	VIOAR	<i>Viola arvensis</i>	25-28 DA-A	BBCH 10-21	100.00	S
	SOLNI	<i>Solanum nigrum</i>	27-28 DA-A	BBCH 10-14	94.80	S
	ECHCG	<i>Echinochloa crus-galli</i>	25-28 DA-A	BBCH 10-14	96.63	S
	SINAR	<i>Sinapsis arvensis</i>	27-28 DA-A	BBCH 10-14	96.67	S
	CAPBP	<i>Capsella bursa-pastoris</i>	27-28 DA-A	BBCH 10-14	100.00	S
	MATIN	<i>Tripleurospermum inodorum</i>	27-28 DA-A	BBCH 10-30	99.80	S
	VERHE	<i>Veronica hederifolia</i>	25-28 DA-A	BBCH 10-14	86.88	S
	STEME	<i>Stellaria media</i>	25-28 DA-A	BBCH 10-31	99.42	S
	BRSNW	<i>Brassica napus</i> (self-sown plant)	25-28 DA-A	BBCH 10-16	91.73	S
	AMARE	<i>Amaranthus retroflexus</i>	26-28 DA-A	BBCH 10-16	98.55	S

In the Polish label following weed species can be accepted.

✓ **for pre-emergence use:** recommended dose – 0.28 L/ha

Susceptible: *Chenopodium album* (CHEAL), *Anthemis arvensis* (ANTAR), *Polygonum persicaria* (POLPE), *Thlaspi arvense* (THLAR), *Capsella bursa-pastoris* (CAPBP), *Tripleurospermum mar. inodorum* (MATIN), *Stellaria media* (STEME), *Amaranthus retroflexus* (AMARE), *Echinochloa crus-galli* (ECHCG), *Solanum nigrum* (SOLNI),

Moderately Susceptible: *Viola arvensis* (VIOAR), *Brassica napus* (self-sown plant) (BRSNW)

✓ **for post-emergence use:** recommended dose – 0.3 L/ha

Susceptible: *Chenopodium album* (CHEAL), *Anthemis arvensis* (ANTAR), *Polygonum persicaria* (POLPE), *Thlaspi arvense* (THLAR), *Viola arvensis* (VIOAR), *Solanum nigrum* (SOLNI), *Sinapsis arvensis* (SINAR), *Capsella bursa-pastoris* (CAPBP), *Tripleurospermum mar. inodorum* (MATIN), *Stellaria media* (STEME), *Brassica napus* (self-sown plant) (BRSNW), *Amaranthus retroflexus* (AMARE)

Moderately Susceptible: *Echinochloa crus-galli* (ECHCG), *Veronica hederifolia* (VERHE), *Brassica napus* (self-sown plant) (BRSNW),

Tolerant: *Polygonum convolvulus* (POLCO)

In the GAP table and label project only, maize can be accepted. Sweet corn can be accepted only on the basis on Article 51 without any trials. There is a lack of 2-3 selectivity studies performed on sweet corn. Because only forage corn (its varieties) for silage, biogas and grain appeared in the studies.

Undesirable effects are not expected on succeeding crops, adjacent crop, part of plants used for propagating purposes and beneficial organisms.

According to the above, the plant protection product CHR/H/IZOXACYP 250 SC can be approved to the market and use in Poland according to proposed range of use – GAP.

Based on submitted data the following regulation on the label is proposed:

Poland

Maize:

Recommended dose at:

0.28 L/ha of CHR/H/IZOXACYP 250 SC – preemergence application once a season in maize, which are corresponding to 70 g a.s./ha (isoxaflutole),

0.30 L/ha of CHR/H/IZOXACYP 250 SC – postemergence application once a season in maize, which are corresponding to 75 g a.s./ha (isoxaflutole).

The product CHR/H/IZOXACYP 250 SC should be use once per season at spring pre- and postemergence. To avoid resistance, products contain active substance with the same group shouldn't be used year after year on the same field.

CHR/H/IZOXACYP 250 SC is to be applied in spring:

BBCH 00-09 and BBCH 11-13 in maize.

Recommended volume of water 200-300 L/ha (maize)

Recommended medium droplet spraying

Use of CHR/H/IZOXACYP 250 SC according to the proposed GAP does not represent a hazard to rotational crops and does not justify a specific labelling. CHR/H/IZOXACYP 250 SC is not persistent in soil nor is it taken up by succeeding crops.

Details will be provided in the dRR Part B Section 3 KCP 6 point 3.2.

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

CHR/H/IZOXACYP 250 SC is a herbicide containing active substance isoxaflutole 250 g/L. The mode of action is based on the inhibition of of Hydroxyphenyl Pyruvate Dioxygenase (HRAC group: 27, legacy F2). This group of herbicides is quite well known and has been applied commercially for decades.

According to Ian Heap's website (<http://www.weedscience.org>) there are only two species which have been reported as resistant to isoxaflutole: *Raphanus raphanistrum* and *Amaranthus tuberculatus* (=A. *rudis*) (Table 1). Both cases have been reported in the Australia and USA with no evidence of resistance in Europe. Taking into account the entire HRAC group 27, 14 cases of weed resistance to 4-HPPD inhibitors in three weed species were reported: *Raphanus raphanistrum*, *Amaranthus tuberculatus* (=A. *rudis*) and *Amaranthus palmeri* (Table 2). All cases reported have been in the Australia and USA with no evidence of resistance in Europe (the risk of developing resistance to 4-HPPD inhibitors, including isoxaflutone) is very low).

According to submitted efficacy data none of the tested weeds showed high tolerance to the product CHR/H/IZOXACYP 250 SC.

CHR/H/IZOXACYP 250 SC is a herbicide containing active substance isoxaflutole 250 g/L, which belong to HRAC group 27 – 4-HPPD inhibitors. According HRAC Mechanism of resistance studies are ongoing.

According to EPPO PP 1/213 (4) Resistance risk analysis weeds usually only produce one generation per year and development of resistance is usually a relatively slow process.

In conclusion, in the applicant's opinion, this level of weeds resistance risk should be considered to be acceptable.

Details will be provided in the dRR Part B Section 3 KCP 6.3 point 3.3.

3.3.2 Adverse effects on treated crops

The applicant submitted 16 reports (in total) showing the results in research into product selectivity carried out in 2020, 2021 and 2022 in maize (8 trials – preemergence application and 8 trials – postemergence application). The 8 selectivity trials (preemergence application) and 14 efficacy trials (preemergence application) in maize were carried out in Poland in 2021 and 2022 on a wide range of commercially grown varieties.

The 8 selectivity trials (postemergence application) and 16 efficacy trials (postemergence application) in maize were carried out in Poland in 2020, 2021 and 2022 on a wide range of commercially grown varieties.

The 8 selectivity trials and 14 efficacy trials (with phytotoxicity assessment) were carried out in maize in Poland in 2021 on a wide range of commercially grown varieties. In one trial (report no. A.T/2021/053/KK) there were observed some phytotoxicity symptoms on tested product and standard. Phytotoxicity have no impact on yield quality and quantity.

The eight selectivity trials and 16 efficacy trials (with phytotoxicity assessment) were carried out on maize in Poland in two seasons 2020 and 2021 on a wide range of commercially grown varieties. In two selectivity trials (report no. A.T/2021/060/KK and A.T/2020/084/KK) and in one efficacy trials (report no. A.T/2021/054/KK) there were observed some phytotoxicity symptoms on tested product and standard. Phytotoxicity have no impact on yield quality and quantity.

Influence of CHR/H/IZOXACYP 250 SC on the yield of grains was evaluated in selectivity research. The yield was evaluated on the basis of harvested grains quantity from one hectare (t/ha). The influence of the tested product on quantity of grain was evaluated in 16 field experiments in in maize (8 trials – preemergence application and 8 trials – postemergence application) in Poland in 2020, 2021 and 2022.

There weren't difference between the treatment objects and standard.

In 3 trials (1 trial in preemergence application, 2 trials in postemergence application) there were phytotoxicity effects (report no. A.T/2021/053/KK, A.T/2021/060/KK and A.T/2020/084/KK). This effects didn't have any negative effect on the yield of maize.

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

3.3.3 Observations on other undesirable or unintended side-effects

Details will be provided in the dRR Part B Section 3 KCP 6.5 point 3.5.

3.4 Methods of analysis (Part B, Section 5)

Analytical methods for determination of Isoxaflutole and relevance of CIPAC methods in CHR/H/IZOXACYP were not evaluated as part of the EU review of isoxaflutole. Therefore all relevant

data are provided and are considered adequate.

3.4.1 Analytical method for the formulation

An overview on the acceptable methods and possible data gaps for analysis of active substance, isoxaflutole, in plant protection product is provided as follows:

	Isoxaflutole
Author(s), year	Partzałek M., 2021
Principle of method	HPLC-DAD
Linearity (n=5) (linear between 1.027 – 41.076 mg/L / range of the declared content)	Primary chromatographic system: Equation of calibration curve: $f(x)=3.77086 \times 10^{-5} x + 0.1116111$ $R = 0.9999831$ $R^2 = 0.9999661$ (range of concentrations: 1.027 – 41.076 µg/mL) Secondary chromatographic system: Equation of calibration curve: $f(x)=3.86531 \times 10^{-5} x + 0.0759925$ $R = 0.9999830$ $R^2 = 0.9999660$ (range of concentrations: 1.027 – 41.076 µg/mL)
Precision – Repeatability Mean N = 5 (%RSD)	Primary chromatographic system: 100% without standard addition: %RSD=0.26%; RSDr=1.69%; Horrat value=0.15 LOQ level: %RSD=1.14%; RSDr=2.68%; Horrat value=0.43 uLOQ level: %RSD=1.28%; RSDr=1.61%; Horrat value=0.80 Secondary chromatographic system: 100% without standard addition: %RSD=0.49%; RSDr=1.69%; Horrat value=0.29 LOQ level: %RSD=2.35%; RSDr=2.68%; Horrat value=0.88 uLOQ level: %RSD=1.41%; RSDr=1.61%; Horrat value=0.88
Accuracy n = 5 (% Recovery)	Primary chromatographic system: Marginal recovery: 98.43 – 102.01% (within the limits: 97-103%) LOQ level: 105.9% uLOQ level: 101.9% The results fulfils the acceptance criterion (90 – 110%). Secondary chromatographic system: Marginal recovery: 98.36 – 101.31% (within the limits: 97-103%) LOQ level: 100.1% uLOQ level: 100.9% The results fulfils the acceptance criterion (90 – 110%).
Interference/ Specificity	Specificity of the method was evaluated based on the analysis of chromatograms for blank samples (placebo) against samples of placebo spiked with isoxaflutole standard. Analysis showed no overlapping of determined substance signal with the signals of matrix components under method conditions hence method specificity criterion is fulfilled.
LOQ	The limit of quantification (LOQ) was defined as the lowest concentration of standard - 1.027 µg/mL, which

	Isoxaflutole
	was determined with an acceptable recovery.
Comment	-

The method for determination of active substances in IZOXAFLUTOLE 250 SC (CHR/H/IZOXACYP) preparation is specific. The validation parameters for linearity, instrument precision, repeatability and accuracy are within the acceptance range. The determined average content of active substance in IZOXAFLUTOLE 250 SC (CHR/H/IZOXACYP) is: 21.659±0.078%.

An overview on the acceptable methods and possible data gaps for analysis of formulant, cyprosulfamide, in plant protection product is provided as follows:

**Methods suitable for the determination of cyprosulfamide in plant protection product
CHR/H/IZOXACYP 250 SC**

	Cyprosulfamide
Author(s), year	Lebek B., 2022
Principle of method	HPLC-DAD
Linearity N=5 (linear between 1.108 – 44.311 mg/L / % range of the declared content) (correlation coefficient, expressed as r)	Primary chromatographic system: Equation of calibration curve: $f(x) = 6.08568 \times 10^{-5} x - 0.104850$ $R = 0.9999272$ $R^2 = 0.9998544$ (range of concentrations: 1.108 – 44.311 µg/mL) Secondary chromatographic system: Equation of calibration curve: $f(x) = 6.31410 \times 10^{-5} x - 0.0781263$ $R = 0.9999120$ $R^2 = 0.9998240$ (range of concentrations: 1.108 – 44.311 µg/mL)
Precision – Repeatability Mean N = 5 (%RSD)	Primary chromatographic system: %RSD=0.13%; RSDr=1.68%; Horrat value = 0.08 LOQ level: %RSD=0.57%; RSDr=2.68%; Horrat value=0.21 uLOQ level: %RSD=0.81%; RSDr=1.61%; Horrat value=0.5 Secondary chromatographic system: %RSD=0.24%; RSDr=1.68%; Horrat value = 0.14 LOQ level: %RSD=1.42%; RSDr=2.68%; Horrat value=0.53 uLOQ level: %RSD=0.57%; RSDr=1.61%; Horrat value=0.35
Accuracy n = 5 (% Recovery)	Primary chromatographic system Marginal recovery: 98.88 - 100.78% (within the limits: 97-103%) LOQ level: 92.9% (average) uLOQ level: 100.8% (average) The results fulfils the acceptance criterion (90 – 110%). Secondary chromatographic system Marginal recovery: 98.30 – 100.27% (within the limits: 97-103%) LOQ level: 92.5% (average) uLOQ level: 100.1% (average) The results fulfils the acceptance criterion (90 – 110%).

	Cyprosulfamide
Interference/ Specificity	Specificity of the method was evaluated based on the analysis of chromatograms for placebo and samples against chromatograms of standard cyprosulfamide and peak purity. Analysis showed no overlapping of determined ingredient signal with the signals of matrix components under method conditions, hence method specificity criterion is fulfilled.
LOQ	The limit of quantification (LOQ) was defined as the lowest concentration of standard – 1.108 µg/mL, which was determined with an acceptable recovery.
Comment	-

The method for determination of formulant cyprosulfamide in IZOXAFLOTOL 250 SC (CHR/H/IZOXACYP) preparation is specific. The validation parameters for linearity, instrument precision, repeatability and accuracy are within the acceptance range. The determined average content of cyprosulfamide in IZOXAFLOTOL 250 SC (CHR/H/IZOXACYP) is: 22.12±0.04%.

3.4.2 Analytical methods for residues

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

Noticed data gaps are:

- none
- ILV for drinking water is required according to Regulation (EU) No 284/2013 (post registration requirement)
- analytical methods for body fluids and tissues are required according to Regulation (EU) No 284/2013 (post registration requirement)

Commodity/crop	Supported/ Not supported
Maize	Supported

Method Validation for Determination of Isoxaflutole and Metabolites in Water, Independent Laboratory Validation for Determination of Isoxaflutole and Metabolites in Drinking Water and Method Validation for Determination of Isoxaflutole and its Metabolite RPA 202248 in Body Fluids and Tissues were provided. Methods are accepted. The data gap has been filled.

3.5 Mammalian toxicology (Part B, Section 6)

TAIZZA PLUS 250 SC (CHR/H/IZOXACYP 250 SC) is classified as Skin Sens 1A / H317; Repr. 2 / H361d

3.5.1 Operator exposure

The predicted exposure values according to EFSA model with using PPE are significantly below 100% of systemic AOEL. Exposure of the operator is acceptable.

Implication for labeling: P280: Wear protective gloves, protective clothing

3.5.2 Worker exposure

According to Guidance on Pesticides Exposure Assessment of Operators, Workers, Residents and Bystanders, (EFSA Journal 2014;12(10):3874) to the calculation used the value of 12500 transfer coefficient (TC (cm²/h) arms, body and legs covered - workwear; bare hands) and 2 hours work/day (only crop inspection and irrigation-type). Having regard to the above values, the predicted exposure values for CHR/H/IZOXACYP 250 SC without PPE are significantly above 100% of systemic AOEL and therefore exposure of the worker with using PPE is acceptable.

3.5.3 Bystander and resident exposure

The predicted exposure significantly below of 100% (when buffer strip 5 m is applied) of systemic AOEL and exposure of the bystander and resident is acceptable.

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

Stability of Residues

Residues of isoxaflutole (sum of isoxaflutole, DKN metabolite and IFT acid), are stable in corn matrices when stored under freezer conditions for 3 months (processed commodities) and for 15 months (raw agricultural commodities)

All samples in the considered supervised residues trials were analysed within 30 days after sampling thus no stability of residues is required.

Residue definitions:

Commission Regulation (EU) No 2015/845 of 27 May 2015: Isoxaflutole (sum of isoxaflutole and its diketonitrile-metabolite, expressed as isoxaflutole.

Plant residue definition for risk assessment (EFSA Journal 2016;14(3):4416):

Conventional crops: RPA 203328

Genetically modified crops: RPA 203328 and RPA 202248

Animal residue definition for monitoring and risk assessment: not required for the representative use

Magnitude of residues in plants

Applicant refers to 5 supervised residues trials performed in 2017 in northern Europe (Eurofins 2017, Dr. Sönke Lakaschus, Sabrina Fritsch). Trials were evaluated and accepted in dRR Part B7, CHR/H/TERIZ 650 WG (Undito 650 WG, Jotamun 650 WG, Metodus 650 WG), Core Assessment- renewal of authorisation, Poland, 2021. These trials are presented in Appendix 2, A.2.1.2.1.4.

Trials GAP: 1 x 0.1 kg as/ha, BBCH0 0-13, PHI N/A, outdoor

Results:

isoxaflutole (RPA 201772): 5 x <0.003 mg/kg (LOD)

RPA 202248: 5 x <0.003 mg/kg (LOD)

RPA 203328: 5 x <0.003 mg/kg (LOD)

LOQ of the method used is 0.01 mg/kg

Additionally refers to studies presented in core assessment and latest supplements of registration report Part B, Section 4: Metabolism and Residues of Adengo 315 SC in 06/11/2015 (Isoxaflutole + Thien-carbazone-methyl + Cyprosulfamide (as safener)). Since the data protection information for these studies has not been confirmed, these studies were not included in the assessment.

Nevertheless sufficient trials are available to support the proposed uses in maize. The residues of isoxaflutole and metabolite RPA 202248 in maize commodities at harvest in the available field trials are below the individual limit of quantifications (LOQs) of 0.01 mg/kg (sum LOQ 0.02 mg/kg) of the validated analytical method. Extrapolation to sweet corn is possible.

The residues arising from the proposed uses will not exceed the MRLs established for maize grain (0.02* mg/kg; Reg.(EU) No 2015/845).

Residue data are valid with regard to storage stability.

Isoxaflutole is usually used together with the safener cyprosulfamide. Critical GAP for the intended uses of CHR/H/IZOXACYP 250 SC is within the EU GAP (EFSA Journal 2016;14(2):4416). The representative formulated product for the EU evaluation was 'Isoxaflutole + Cyprosulfamide SC 480 (Merlin Flexx)', a suspension concentrate (SC) containing 240 g/L isoxaflutole and 240 g/L cyprosulfamide as a safener. Use Isoxaflutole with the Cyprosulfamide as safener is acceptable.

Additionally, field trials assessed in Adengo were conducted with Cyprosulfamide. Data out of protection should be confirmed (use with a safener).

Livestock Feeding Studies:

According to the dietary burden calculation for isoxaflutole (EFSA dietary burden calculator (2017)) and low residues in maize, no livestock feeding studies are necessary

Industrial Processing and/or Household Preparation:

EFSA Journal 2016;14(2):4416: *Processing studies are not triggered since residue levels of RPA 203328 in maize grain are <0.1 mg/kg. This assessment should be reconsidered pending the outcome of the requested hydrolysis study addressing the nature of RPA 203328 residues in processed commodities.*

No additionally data is required.

Residues in Representative Succeeding Crops:

No additional studies on rotational crops are considered necessary.

No restrictions are necessary.

The consumer risk assessment for isoxaflutole was performed with the EFSA PRIMo rev.3.1. No chronic and acute intake concerns were identified.

RPA 203328:

Additionally zRMS has calculated of the TMDI based on the STMR values and ADI for RPA 203328. No chronic intake concerns were identified.

EFSA Journal 2016;14(2):4416:

The additional intake through drinking water of RPA 203328 is less than 1% of the ADI of RPA 203328 for all considered consumer groups.

PHI: not required

The intended use evaluated in this dossier can be authorized.

3.6.1 Consumer exposure

Table 3.6-4: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	0.7 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	0.4 % (based on the STMR from studies)
IESTI (% ARfD) according to EFSA PRIMo*	0.1 % (based on the STMR from studies) 0.5 % (based on the STMR from studies)

The proposed uses of isoxaflutole (100 g as/ha) in the formulation CHR/H/IZOXACYP 250 SC do not represent unacceptable acute and chronic risks for the consumer.

ZRMS calculation (RPA 203328):

The calculation of the TMDI was performed based on the STMR values and ADI for RPA 203328.

Input values for the consumer risk assessment:

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: RPA 203328 ADI: 0.8 mg/kg bw per day		
Maize (grain)	0.01	STMR (Table 7.2-9)
Sweet corn	0.01	Extrapolated from maize

Consumer risk assessment:

TMDI (% ADI) according to EFSA PRIMo rev.3.1	0.0 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo* rev.3.1	Not provided, not required

EFSA Journal 2016;14(2):4416:

The additional intake through drinking water of RPA203328 is less than 1% of the ADI of RPA 203328 for all considered consumer groups.

The proposed uses of isoxaflutole in the formulation CHR/H/IZOXACYP 250 SC do not represent unacceptable acute and chronic risks for the consumer.

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

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

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

The PEC_{soil} of isoxaflutole and its metabolites in soil have been assessed with the DT50 values established in the EU review. Based on the recommended use rate of 0.4L [product]/ha (473.3 g prod/ha).

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

According to PEC_{gw} modelling with FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 a ground water contamination of the active substance isoxaflutole at a concentration of $\geq 0.1 \mu\text{g/L}$ is not expected in use on winter/spring cereals. For the metabolites a groundwater concentration of $\geq 0.1 \mu\text{g/L}$ can not be excluded. The risk assessment for metabolites was performed in B-10 section and concluded that there is no risk to consumer.

W celu ochrony wód gruntowych/nie stosować tego lub żadnego innego produktu zawierającego isoxaflutol częściej niż raz na trzy lata

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

The PEC surface water and sediment of isoxaflutole and its metabolites in surface water (PEC_{sw} and PEC_{sed}) have been assessed with the FOCUS SW and the DT50 water/sediment values established in the EU review. Based on the maximum recommended use rate of 100 g a.s. isoxaflutole/ha the maximum PEC values for surface water and sediment have been calculated according to FOCUS Steps 1-4 for the parents and the metabolites.

The results for PEC surface water for the active substance and its metabolites were used for the ecotoxicological risk assessment

3.7.4 Ecotoxicology (Part B, Section 9)

3.7.4.1 Effects on terrestrial vertebrates

CHR/H/IZOXACYP 250 SC pose no unacceptable acute and long term risk to birds and mammals and other terrestrial vertebrates used according to the label.

3.7.4.2 Effects on aquatic species

Studies on the toxicity to aquatic species have been carried out with active substance isoxaflutole. Full details of these studies are provided in the respective EU DAR and related documents. Effects on aquatic species of CHR/H/IZOXACYP 250 SC were not evaluated as part of the EU assessment of isoxaflutole. CHR/H/IZOXACYP 250 SC pose no unacceptable risk to aquatic organisms according to the label with appropriate buffer zone:

20 meters vegetative and no-spray buffer zone.

3.7.4.3 Effects on bees

Studies on the toxicity for bees have been carried out with the active substance isoxaflutole. Full details of these studies are provided in the respective EU DAR and related documents. Effects on bees of CHR/H/IZOXACYP were not evaluated as part of the EU assessment of isoxaflutole. CHR/H/IZOXACYP pose no un-acceptable risk to bees according to the label.

3.7.4.4 Effects on other arthropod species other than bees

Studies on the toxicity for other arthropod species have been carried out with the active substance isoxaflutole. Full details of these studies are provided in the respective EU DAR and related documents. Effects on non-target arthropods of CHR/H/IZOXACYP were not evaluated as part of the EU assessment of isoxaflutole. CHR/H/IZOXACYP pose no un-acceptable risk to NTA according to the label.

3.7.4.5 Effects on soil organisms

Studies on the toxicity for earthworms have been carried out with the active substance isoxaflutole. Full details of these studies are provided in the respective EU DAR and related documents. Effects on earth-

worms of CHR/H/IZOXACYP were not evaluated as part of the EU assessment of isoxaflutole. CHR/H/IZOXACYP pose no un-acceptable risk to earthworms according to the label.

CHR/H/IZOXACYP 250 SC pose no unacceptable risk to non-target soil meso- and macrofauna and microbial activity according to the label.

3.7.4.6 Effects on non-target terrestrial plants

Studies on the toxicity to non-target terrestrial plants have been carried out with active substance isoxaflutole. Full details of these studies are provided in the respective EU DAR and related documents. Effects on non-target terrestrial plants of CHR/H/IZOXACYP were not evaluated as part of the EU assessment of isoxaflutole.

Based on the predicted rates of CHR/H/IZOXACYP in off-field areas, the TER values describing the risk for non-target plants following exposure to CHR/H/IZOXACYP according to the GAP of the formulation CHR/H/IZOXACYP achieve the acceptability criteria $TER \geq 1$ based on SSD risk refinement, with applying:

- 5 m without use of drift reducing nozzles
- 1 m and use of 90 % drift reducing nozzles

3.7.4.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.8 Relevance of metabolites (Part B, Section 10)

The metabolite RPA 203328 of isoxaflutole is predicted to occur in groundwater at concentrations above 0.1 µg/L (see PART B Section 10 of CHR/H/IZOXACYP 250 SC dRR). Assessment of the relevance of this metabolite according.

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

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

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

Appendix 1 Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.
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Appendix 2 Copy of the product label

Załącznik do zezwolenia MRiRW nr R - / z dnia 2022 r.

Posiadacz zezwolenia:

INNIVIGO Sp. z o.o., Aleje Jerozolimskie 178, 02-486 Warszawa, tel.: +48 22 468 26 70, e-mail: biuro@innvigo.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

...

TAIZZA PLUS 250 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

izoksaflutol (związek z grupy pochodnych izoksazoli) – 250 g/l (21,1 %)

Sejfner:

cyprosulfamid – 250 g/l (21,1 %)

Inne substancje niebezpieczne niebędące substancją czynną:

2-methylisothiazol-3(2H)-one

Zezwolenie MRiRW nr R - / z dnia .2022 r.

	
Uwaga	
H317 H361d H410	Może powodować reakcję alergiczną skóry. Podejrzewa się, że działa szkodliwie na dziecko w łonie matki. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P280 P302 + P352 P308 + P313	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody/mydłem. W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P333 + P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

P391	Zebrać rozsypany produkt.
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OPIS DZIAŁANIA

HERBICYD w formie stężonej zawiesiny (SC) do rozcieńczania wodą, stosowany doglebowo lub nalistnie. Zawiera substancję aktywną izoksafłutol, do stosowania w zwalczaniu szerokiego spektrum chwastów jednoliściennych i dwuliściennych w kukurydzy. Środek zawiera w swoim składzie sejfner – cyprosulfamid, odpowiedzialny za detoksykację użytych substancji aktywnych w kukurydzy, Zgodnie z klasyfikacją HRAC substancja czynna izoksafłutol zaliczana jest do grupy 27. Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

DZIAŁANIE NA CHWASTY

Środek zawiera substancję czynną izoksafłutol, która zaliczana jest do inhibitorów enzymu odpowiedzialnego za biosyntezę barwników fotoaktywnych, co w konsekwencji prowadzi do zahamowania biosyntezy karotenoidów w roślinach chwastów, objawiającego się bieleniem liści.

Izoksafłutol pobierany jest przez korzenie, kielki i liście chwastów. Pierwsze objawy działania substancji czynnej widoczne są po 5-7 dniach od wykonania zabiegu. Zamieranie chwastów następuje po około 14 dniach.

Dobre uwilgotnienie gleby oraz korzystne warunki dla wzrostu i rozwoju kukurydzy sprzyjają działaniu środka.

Środek stosowany pojedynczo przedwzchodowo w dawce: 0,28 l/ha

Chwasty wrażliwe:	chwastnica jednostronna, gwiazdnica pospolita, komosa biała, maruna bezwonna, psianka czarna, rdest plamisty, rumian polny, szarłat szorstki, tasznik pospolity, tobołki polne,
Gatunki średnio wrażliwe	fiołek polny, samosiewy rzepaku

Środek stosowany pojedynczo powzchodowo w dawce: 0,3 l/ha

Chwasty wrażliwe:	fiołek polny, gorczyca polna, gwiazdnica pospolita, komosa biała, maruna bezwonna, psianka czarna, rdest plamisty, rumian polny, szarłat szorstki, tasznik pospolity, tobołki polne,
Gatunki średnio wrażliwe	chwastnica jednostronna, przetacznik bluszczykowy, samosiewy rzepaku,
Gatunki odporne	rdestówka powojowata

STOSOWANIE ŚRODKA

Kukurydza (z przeznaczeniem na kiszonkę, biogaz i ziarno).

Stosowanie przedwzchodowe

Zalecana/maksymalna dawka środka dla jednorazowego zastosowania: 0,28 l/ha

Termin stosowania: po siewie, ale przed wschodami kukurydzy (BBCH 00-09)

Liczba zabiegów: 1

Zalecana ilość wody: 200 - 300 l/ha

Zalecane opryskiwanie: średniokropliste.

Stosowanie powzchodowe

Zalecana/maksymalna dawka środka dla jednorazowego zastosowania: 0,3 l/ha

Termin stosowania: od fazy pierwszego liścia do fazy trzech liści (BBCH 11-13)

Liczba zabiegów: 1

Zalecana ilość wody: 200 - 300 l/ha

Zalecane opryskiwanie: średniokropliste.

NASTĘPSTWO ROŚLIN

Po zbiorze kukurydzy uprawianej w normalnych warunkach wegetacji, odchwaszczonej środkiem Taizza Plus 250 SC po wykonaniu głębokiej orki oraz zespołu zalecanych uprawek przedsiewnych uprawiać można następujące rośliny rolnicze: pszenicę ozimą, pszenicę jara, pszenicę durum (ozimą, jara), jęczmień ozimy, jęczmień jary, fasolę, groch, rośliny włókniste, słonecznik, buraki cukrowe, ziemniaki, soję, kukurydzę (na ziarno, kiszonkę), kukurydzę cukrową oraz sorgo. W przypadku uprawy roślin wrażliwych takich jak: burak, bobowate, rzepak ozimy, słonecznik warzywa oraz wcześniej sianych zbóż ozimych w warunkach niekorzystnych dla rozkładu środka (gleby łatwo przesychające, o pH < 6.0, gleby o wysokiej zawartości substancji organicznej >4.0%, niskiej aktywności biologicznej, wyjątkowo niskich temperaturach w okresie zimowym, wyjątkowo niskiej wilgotności gleby latem i/lub jesienią i/lub zimą, nakładanie się powierzchni opryskanej preparatem) możliwe jest wystąpienie uszkodzeń rośliny uprawnej.

W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem Taizza Plus 250 SC (np. w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na tym samym polu po wykonaniu orki na głębokość 20 cm można uprawiać tylko kukurydzę.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

Nie dotyczy

1. W przypadku suszy skuteczność środka może ulec obniżeniu wskutek braku możliwości przedostania się substancji czynnej do systemu korzeniowego chwastów.
2. W niekorzystnych warunkach pogodowych (np. susza, skrajnie niskie lub wysokie temperatury, duże wahania temperatur pomiędzy nocą a dniem) na niektórych odmianach kukurydzy środek może powodować przemijające objawy fitotoksyczności, nie mające wpływu na plon.
3. Nie zaleca się stosowania środka w liniach wsobnych kukurydzy, na plantacjach nasiennych oraz w kukurydzy cukrowej bez uprzedniego wykonania próbnego zabiegu w celu sprawdzenia, czy nie występują objawy uszkodzenia roślin lub bez skontaktowania się z doradcą albo przedstawicielem posiadacza zezwolenia.
4. Strategia zarządzania odpornością
W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:
 - postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin
 - stosować środek w zalecanej dawce, w zalecany terminie zapewniającym optymalne zwalczanie chwastów,
 - dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
 - stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
 - stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
 - stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
 - stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
 - dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
 - używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
 - używać kwalifikowanego materiału siewnego,
 - czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,

- informować posiadacza zezwolenia o nie satysfakcjonującym zwalczaniu chwastów,
 - w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.
5. Środka nie stosować:
- w czasie opadu deszczu lub przed spodziewanym deszczem,
 - w przypadku spodziewanych przymrozków lub w warunkach panującej bądź spodziewanej suszy,
 - podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.
 - w mieszaniu z innymi środkami ochrony roślin, nawozami i dodatkami wspomagającymi
6. Podczas stosowania środka nie dopuścić do:
- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlewniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. Opryskiwać z włączonym mieszadłem.

Ciecz użytkową sporządzić bezpośrednio przed użyciem.

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

Po pracy aparaturę dokładnie wymyć.

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy :

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

Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej. W przypadku mycia aparatury przy użyciu środków przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną 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 użytkowej i które zwróciły się o taką informację.

Przed użyciem zapoznać się ze specjalnymi środkami ostrożności.

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

Nie wdychać rozpylonej cieczy.

Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

W czasie oprysku należy zastosować co najmniej 5 metrową strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.

W czasie oprysku należy zastosować techniki zmniejszające znoszenie preparatu (dysze antyznoszeniowe).

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

Zakaz wejścia przez osoby postronne na teren poddany opryskowi.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

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

W celu ochrony wód gruntowych/nie stosować tego lub żadnego innego produktu zawierającego isoksaflutol częściej niż raz na trzy lata

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

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

- 5 m od terenów nieużytkowanych rolniczo lub
- 1 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.

WARUNKI PRZECZYSZCZANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0 °C - 30°C.

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

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

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

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza należy pokazać pojemnik lub etykietę.

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

W przypadku połknięcia: W przypadku złego samopoczucia skontaktować się

Z ośrodkiem zatruc lub z lekarzem. Wypłukać usta.

W przypadku dostania się na skórę: Umyć dużą ilością wody z mydłem.

W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności – 2 lata

Data produkcji

Zawartość netto

Nr partii

Załącznik do zezwolenia MRiRW nr R - / z dnia 2022 r.

Posiadacz zezwolenia:

INNVIGO Sp. z o.o., Aleje Jerozolimskie 178, 02-486 Warszawa, tel.: +48 22 468 26 70, e-mail: biuro@innvigo.com

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

...

METIDA PLUS 250 SC

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

izoksafłutol (związek z grupy pochodnych izoksazoli) – 250 g/l (21,1 %)


Sejfner:

cyprosulfamid – 250 g/l (21,1 %)

Inne substancje niebezpieczne niebędące substancją czynną:

2-methylisothiazol-3(2H)-one

Zezwolenie MRiRW nr R - / z dnia .2022 r.

	
Uwaga	
H317 H361d H410	Może powodować reakcję alergiczną skóry. Podejrzewa się, że działa szkodliwie na dziecko w łonie matki. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P280 P302 + P352 P308 +P313	Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody/mydłem. W przypadku narażenia lub styczości: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P333 + P313 P391	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza. Zebrać rozsypany produkt.

OPIS DZIAŁANIA

HERBICYD w formie stężonej zawiesiny (SC) do rozcieńczania wodą, stosowany dogłębowo lub nalistnie., Zawiera substancję aktywną izoksafłutol, do stosowania w zwalczaniu szerokiego spektrum chwastów jednoliściennych i dwuliściennych w kukurydzy. Środek zawiera w swoim składzie sejfner – cyprosulfamid, odpowiedzialny za detoksykację użytych substancji aktywnych w kukurydzy,

Zgodnie z klasyfikacją HRAC substancja czynna izoksaflutol zaliczana jest do grupy 27.

Środek przeznaczony do stosowania przy użyciu samobieźnego lub ciągnikowego opryskiwacza polowego.

DZIAŁANIE NA CHWASTY

Środek zawiera substancję czynną izoksaflutol, która zaliczana jest do inhibitorów enzymu odpowiedzialnego za biosyntezę barwników fotoaktywnych, co w konsekwencji prowadzi do zahamowania biosyntezy karotenoidów w roślinach chwastów, objawiającego się bieleniem liści.

Izoksaflutol pobierany jest przez korzenie, kielki i liścienie chwastów. Pierwsze objawy działania substancji czynnej widoczne są po 5-7 dniach od wykonania zabiegu. Zamieranie chwastów następuje po około 14 dniach.

Dobre uwilgotnienie gleby oraz korzystne warunki dla wzrostu i rozwoju kukurydzy sprzyjają działaniu środka.

Środek stosowany pojedynczo przedwzchodowo w dawce: 0,28 l/ha

Chwasty wrażliwe:	chwastnica jednostronna, gwiazdnica pospolita, komosa biała, maruna bezwonna, psianka czarna, rdest plamisty, rumian polny, szarłat szorstki, tasznik pospolity, tobołki polne,
Gatunki średnio wrażliwe	fiołek polny, samosiewy rzepaku

Środek stosowany pojedynczo powzchodowo w dawce: 0,3 l/ha

Chwasty wrażliwe:	fiołek polny, gorczyca polna, gwiazdnica pospolita, komosa biała, maruna bezwonna, psianka czarna, rdest plamisty, rumian polny, szarłat szorstki, tasznik pospolity, tobołki polne,
Gatunki średnio wrażliwe	chwastnica jednostronna, przetacznik bluszczykowy, samosiewy rzepaku,
Gatunki odporne	rdestówka powojowata

STOSOWANIE ŚRODKA

Kukurydza (z przeznaczeniem na kiszonkę, biogaz i ziarno).

Stosowanie przedwzchodowe

Zalecana/maksymalna dawka środka dla jednorazowego zastosowania: 0,28 l/ha

Termin stosowania: po siewie, ale przed wschodami kukurydzy (BBCH 00-09)

Liczba zabiegów: 1

Zalecana ilość wody: 200 - 300 l/ha

Zalecane opryskiwanie: średniokropliste.

Stosowanie powzchodowe

Zalecana/maksymalna dawka środka dla jednorazowego zastosowania: 0,3 l/ha

Termin stosowania: od fazy pierwszego liścia do fazy trzech liści (BBCH 11-13)

Liczba zabiegów: 1

Zalecana ilość wody: 200 - 300 l/ha

Zalecane opryskiwanie: średniokropliste.

NASTĘPSTWO ROŚLIN

Po zbiorze kukurydzy uprawianej w normalnych warunkach wegetacji, odchwaszczonej środkiem Metida Plus 250 SC po wykonaniu głębokiej orki oraz zespołu zalecanych uprawek przedsięwziętych uprawiać

można następujące rośliny rolnicze: pszenicę ozimą, pszenicę jary, pszenicę durum (ozimą, jary), jęczmień ozimy, jęczmień jary, fasolę, groch, rośliny włókniste, słonecznik, buraki cukrowe, ziemniaki, soję, kukurydzę (na ziarno, kiszonkę), kukurydzę cukrową oraz sorgo. W przypadku uprawy roślin wrażliwych takich jak: burak, bobowate, rzepak ozimy, słonecznik warzywa oraz wcześniej sianych zbóż ozimych w warunkach niekorzystnych dla rozkładu środka (gleby łatwo przesychające, o pH < 6.0, gleby o wysokiej zawartości substancji organicznej >4.0%, niskiej aktywności biologicznej, wyjątkowo niskich temperaturach w okresie zimowym, wyjątkowo niskiej wilgotności gleby latem i/lub jesienią i/lub zimą, nakładanie się powierzchni opryskanej preparatem) możliwe jest wystąpienie uszkodzeń rośliny uprawnej. W przypadku konieczności wcześniejszego zaorania plantacji potraktowanej środkiem Metida Plus 250 SC (np. w wyniku uszkodzenia kukurydzy przez grad, choroby, szkodniki lub przymrozki) na tym samym polu po wykonaniu orki na głębokość 20 cm można uprawiać tylko kukurydzę.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

Nie dotyczy

7. W przypadku suszy skuteczność środka może ulec obniżeniu wskutek braku możliwości przedostania się substancji czynnej do systemu korzeniowego chwastów.
8. W niekorzystnych warunkach pogodowych (np. susza, skrajnie niskie lub wysokie temperatury, duże wahania temperatur pomiędzy nocą a dniem) na niektórych odmianach kukurydzy środek może powodować przemijające objawy fitotoksyczności, nie mające wpływu na plon.
9. Nie zaleca się stosowania środka w liniach wsobnych kukurydzy, na plantacjach nasiennych oraz w kukurydzy cukrowej bez uprzedniego wykonania próbnego zabiegu w celu sprawdzenia, czy nie występują objawy uszkodzenia roślin lub bez skontaktowania się z doradcą albo przedstawicielem posiadacza zezwolenia.
10. Strategia zarządzania odpornością
W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:
 - postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin
 - stosować środek w zalecanej dawce, w zalecany terminie zapewniającym optymalne zwalczanie chwastów,
 - dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
 - stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
 - stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
 - stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
 - stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
 - dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
 - używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
 - używać kwalifikowanego materiału siewnego,
 - czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
 - informować posiadacza zezwolenia o nie satysfakcjonującym zwalczaniu chwastów,
 - w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.
11. Środka nie stosować:
 - w czasie opadu deszczu lub przed spodziewanym deszczem,

- w przypadku spodziewanych przymrozków lub w warunkach panującej bądź spodziewanej suszy,
 - podczas wiatru stwarzającego możliwość znoszenia cieczy użytkowej na sąsiednie rośliny uprawne.
 - w mieszaniu z innymi środkami ochrony roślin, nawozami i dodatkami wspomagającymi
12. Podczas stosowania środka nie dopuścić do:
- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. Opryskiwać z włączonym mieszadłem.

Ciecz użytkową sporządzić bezpośrednio przed użyciem.

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

Po pracy aparaturę dokładnie wymyć.

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy :

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

Z wodą użytą do mycia aparatury należy postąpić tak, jak z resztkami cieczy użytkowej. W przypadku mycia aparatury przy użyciu środków przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną 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 użytkowej i które zwróciły się o taką informację.

Przed użyciem zapoznać się ze specjalnymi środkami ostrożności.

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

Nie wdychać rozpylonej cieczy.

Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

W czasie oprysku należy zastosować co najmniej 5 metrową strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.

W czasie oprysku należy zastosować techniki zmniejszające znoszenie preparatu (dysze antyznoszeniowe).

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
Zakaz wejścia przez osoby postronne na teren poddany opryskowi.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

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

W celu ochrony wód gruntowych/nie stosować tego lub żadnego innego produktu zawierającego isoksafłutol częściej niż raz na trzy lata.

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- 5 m od terenów nieużytkowanych rolniczo lub
- 1 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
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Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

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W przypadku połknięcia: W przypadku złego samopoczucia skontaktować się

Z ośrodkiem zatruc lub z lekarzem. Wypłukać usta.

W przypadku dostania się na skórę: Umyć dużą ilością wody z mydłem.

W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności – 2 lata

Data produkcji

Zawartość netto

Nr partii

Appendix 3 Letter of Access

Confidential information or data are provided separately (Part C).

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1/01	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 2.1/02	Knapik I.	2021	Determination of physicochemical properties after accelerated storage test ICB/58/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 2.1/03	Lebek B.	2022	Determination of physicochemical properties after shelf-life test ICB/13/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 2.2.1	Buczkowski D.	2021	Determination of explosive properties BW-13/21 Testing facility: Lukasiwicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland	N	Y	Data/study report never submitted before to Poland	Chemrol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 2.2.2	Flasińska P.	2021	Determination of oxidizing properties and auto-ignition temperature BC-18/21 Testing facility: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.3.1	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.3.2	Flasińska P.	2021	Determination of oxidizing properties and auto-ignition temperature BC-18/21 Testing facility: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.4.1/01	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.4.1/02	Knapik I.	2021	Determination of physicochemical properties after accelerated storage test ICB/58/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.4.1/03	Łebek B.	2022	Determination of physicochemical properties after shelf-life test	N	Y	Data/study report never submitted before to Poland	Chemirol

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
			ICB/13/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished				
KCP 2.4.2/01	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.4.2/02	Knapik I.	2021	Determination of physicochemical properties after accelerated storage test ICB/58/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.4.2/03	Łebek B.	2022	Determination of physicochemical properties after shelf-life test ICB/13/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.5.1	Arevalo E.	2021	Viscosity determination BF-21/21 Testing facility: Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Warsaw, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.5.2	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.6.1	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021	N	Y	Data/study report never submitted before to Poland	Chemirol

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
			Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished				
KCP 2.7.1/01	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.7.1/02	Knapik I.	2021	Determination of physicochemical properties after accelerated storage test ICB/58/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.7.3/01	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.7.3/02	Knapik I.	2021	Determination of physicochemical properties after accelerated storage test ICB/58/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.7.3/03	Łebek B.	2022	Determination of physicochemical properties after shelf-life test ICB/13/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.7.3/04	Łebek B.	2022	Validation of analytical method for Izoaxflutole 250 SC (CHR/H/IZOXACYP 250 SC) for determination of cypro-sulfamide	N	Y	Data/study report never submitted before to Poland	Chemirol

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
			Company Report No ICB/6/2022 ICB Pharma, 10 Lema Street, 43-600 Jaworzno Poland GLP Unpublished				
KCP 2.7.4	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.7.5	Łebek B.	2022	Determination of physicochemical properties after shelf-life test ICB/13/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.2	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.3.1/01	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.3.1/02	Knapik I.	2021	Determination of physicochemical properties after accelerated storage test ICB/58/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.3.1/03	Łebek B.	2022	Determination of physicochemical properties after shelf-life test ICB/13/2021	N	Y	Data/study report never submitted before to Poland	Chemirol

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
			Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished				
KCP 2.8.3.2/01	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.3.2/02	Knapik I.	2021	Determination of physicochemical properties after accelerated storage test ICB/58/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.3.2/03	Łebek B.	2022	Determination of physicochemical properties after shelf-life test ICB/13/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.5.1.1	Łebek B.	2022	Determination of physicochemical properties after shelf-life test ICB/13/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.5.1.2/01	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.5.1.2/02	Knapik I.	2021	Determination of physicochemical properties after accelerated storage test ICB/58/2021	N	Y	Data/study report never submitted before to Poland	Chemirol

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
			Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished				
KCP 2.8.5.1.2/03	Łebek B.	2022	Determination of physicochemical properties after shelf-life test ICB/13/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.7.2/01	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.7.2/02	Knapik I.	2021	Determination of physicochemical properties after accelerated storage test ICB/58/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.8.7.2/03	Łebek B.	2022	Determination of physicochemical properties after shelf-life test ICB/13/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.11/01	Patrzalek M.	2021	Determination of physicochemical properties ICB/11/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.11/02	Knapik I.	2021	Determination of physicochemical properties after accelerated storage test ICB/58/2021	N	Y	Data/study report never submitted before to Poland	Chemirol

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
			Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished				
KCP 2.11/03	Łebek B.	2022	Determination of physicochemical properties after shelf-life test ICB/13/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 2.1 KCP 2.4.1 KCP 2.4.2 KCP 2.7.3 KCP 2.7.5 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.1 KCP 2.8.5.1.2 KCP 2.8.7.2 KCP 2.11	Łebek B.	2023	Determination of physicochemical properties after shelf-life test ICB/14/2021 Testing Facility: ICB Pharma, Jaworzno, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 5.1.1/0	Patrzalek M.	2021	Validation of analytical method for Izoxaflutole 250 SC (CHR/H/IZOXACYP 250 SC) for determination of isoxaflutole Company Report No ICB/10/2021 ICB Pharma Jaworzno Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 5.1.1/02	Łebek B.	2022	Validation of analytical method for Izoxaflutole 250 SC (CHR/H/IZOXACYP 250 SC) for determination of cyprosulfamide Company Report No ICB/6/2022 ICB Pharma, 10 Lema Street, 43-600 Jaworzno Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2/01	Ivanoc E., Ezeobi-Chris C	2025	Independent Laboratory Validation for Determination of Isoxaflutole and Metabolites in Drinking Water S23-104465(EAG-2301V) Eurofins Agrosience ServicesChem GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł
KCP 5.2/02	Asekunowo J.,	2025 2024	Method Validation for Determination of Isoxaflutole and its Metabolite RPA 202248 in Body Fluids and Tissues S23-104329 Eurofins Agrosience ServicesChem GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł
KCP 5.2/02	Asekunowo J.,	2025	Report Amendment No.1 Method Validation for Determination of Isoxaflutole and Metabolites in Water Eurofins Agrosience ServicesChem GmbH GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/IZOXACYP (Isoxaflutole g/L) pre-emergence in maize SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-433-336FE GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/IZOXACYP (Isoxaflutole g/L) pre-emergence in maize SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz	N	Y	Data/study report never submitted before to Poland	Chemiroł 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
			Report no.: SRPL21-434-336FE GEP - yes Unpublished				
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) pre-emergence in maize SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-435-336FE GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) pre-emergence in maize SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-436-336FE GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Joanna Guzińska	2022	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland, 2022. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2022/002/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Joanna Guzińska	2022	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds,	N	Y	Data/study report never submitted before to Poland	Chemiroł 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
			Poland, 2022. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2022/003/KK GEP - yes Unpublished				
KCP 6.2	Joanna Guzińska	2022	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland, 2022. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2022/004/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Joanna Guzińska	2022	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland, 2022. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2022/005/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł 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
KCP 6.2	Joanna Guzińska	2022	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland, 2022. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2022/006/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Robert Idziak	2022	Assessment of efficacy of herbicide CHR/H/IZOXACYP 250 SC applied preemergence in maize Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/22/K/20/Br/01 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Robert Idziak	2022	Assessment of efficacy of herbicide CHR/H/IZOXACYP 250 SC applied preemergence in maize Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/22/K/20/Zł/02 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł 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
KCP 6.2	Robert Idziak	2022	Assessment of efficacy of herbicide CHR/H/IZOXACYP 250 SC applied preemergence in maize Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/22/K/20/Gr/03 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Robert Idziak	2022	Assessment of efficacy of herbicide CHR/H/IZOXACYP 250 SC applied preemergence in maize Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/22/K/20/Ce/04 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Robert Idziak	2022	Assessment of efficacy of herbicide CHR/H/IZOXACYP 250 SC applied preemergence in maize Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/22/K/20/Mr/05 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250	N	Y	Data/study report never sub-	Chemiroł Sp.

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
			SC when applied into maize to control of weeds, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/081/KK GEP - yes Unpublished			mitted before to Poland	z o.o.
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/082/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Joanna Guzińska	2021	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/054/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Joanna Guzińska	2021	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland,	N	Y	Data/study report never submitted before to Poland	Chemiroł 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
			2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/055/KK GEP - yes Unpublished				
KCP 6.2	Joanna Guzińska	2021	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/056/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Joanna Guzińska	2021	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/057/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland, 2021.	N	Y	Data/study report never submitted before to Poland	Chemiroł 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
			A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/059/KK GEP - yes Unpublished				
KCP 6.2	Joanna Guzińska	2020	Efficacy evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize to control of weeds, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/103/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-437-336FE GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-438-336FE	N	Y	Data/study report never submitted before to Poland	Chemiroł 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
			GEP - yes Unpublished				
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-439-336FE GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-440-336FE GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Zdzisław Jaskólski	2021	Efficacy and selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-441-336FE GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Robert Idziak	2022	Assessment of efficacy of herbicide CHR/H/IZOXACYP 250 SC applied post-emergence in maize Poznań University of Life Sciences, Research and Education Center Gorzyń,	N	Y	Data/study report never submitted before to Poland	Chemiroł 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
			Wojska Polskiego 28, 60-637 Poznań Report no.: AH/22/K/20/Jab/01 GEP - yes Unpublished				
KCP 6.2	Robert Idziak	2022	Assessment of efficacy of herbicide CHR/H/IZOXACYP 250 SC applied post-emergence in maize Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/22/K/20/Ma/02 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.2	Robert Idziak	2022	Assessment of efficacy of herbicide CHR/H/IZOXACYP 250 SC applied post-emergence in maize Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/22/K/20/NW/03 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.4	Joanna Guzińska	2021	Selectivity evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied pre-emergence to maize, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/052/KK	N	Y	Data/study report never submitted before to Poland	Chemiroł 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
			GEP - yes Unpublished				
KCP 6.4	Joanna Guzińska	2021	Selectivity evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied pre-emergence to maize, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/053/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol Sp. z o.o.
KCP 6.4	Agnieszka Fali-gowska	2021	The evaluation of selectivity of herbicide CHR/H/IZOXACYP in maize Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/21/K/17/Zł/01 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol Sp. z o.o.
KCP 6.4	Agnieszka Fali-gowska	2021	The evaluation of selectivity of herbicide CHR/H/IZOXACYP in maize Poznań University of Life Sciences, Research and Education Center Gorzyń, Wojska Polskiego 28, 60-637 Poznań Report no.: AH/21/K/17/Gr/02 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol 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
KCP 6.4	Zdzisław Jaskólski	2022	Selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) pre-emergence in maize. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Report no.: CHR_H_IZOXACYP22_SEL_PL01 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.4	Zdzisław Jaskólski	2022	Selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) pre-emergence in maize. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Report no.: CHR_H_IZOXACYP22_SEL_PL02 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.4	Zdzisław Jaskólski	2022	Selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) pre-emergence in maize. SynTech Research Poland Sp. z o.o. 69/1 Jagiellonska 85-027 Bydgoszcz Report no.: CHR_H_IZOXACYP22_SEL_PL03 GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.4	Zdzisław Jaskólski	2022	Selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) pre-emergence in maize. SynTech Research Poland Sp. z o.o.	N	Y	Data/study report never submitted before to Poland	Chemiroł 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
			69/1 Jagiellonska 85-027 Bydgoszcz Report no.: CHR_H_IZOXACYP22_SEL_PL04 GEP - yes Unpublished				
KCP 6.4	Joanna Guzińska	2021	Selectivity evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied post-emergence to maize, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/060/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol Sp. z o.o.
KCP 6.4	Joanna Guzińska	2021	Selectivity evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied post-emergence to maize, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2021/061/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol Sp. z o.o.
KCP 6.4	Joanna Guzińska	2021	Selectivity evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied post-emergence to maize, Poland, 2021. A.T Sp. z o.o. ul. Przemysłowa 3	N	Y	Data/study report never submitted before to Poland	Chemirol 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
			88-300 Mogilno Report no.: A.T/2021/062/KK GEP - yes Unpublished				
KCP 6.4	Joanna Guzińska	2020	Selectivity evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/083/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.4	Joanna Guzińska	2020	Selectivity evaluation of herbicide CHR/H/IZOXACYP 250 SC when applied into maize, Poland, 2020. A.T Sp. z o.o. ul. Przemysłowa 3 88-300 Mogilno Report no.: A.T/2020/084/KK GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.4	Zdzisław Jaskólski	2021	Selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-442-336FE GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.

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KCP 6.4	Zdzisław Jaskólski	2021	Selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-443-336FE GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.4	Zdzisław Jaskólski	2021	Selectivity of CHR/H/IZOXACYP (Izoxaflutole g/L) post-emergence in maize. SynTech Research Poland Sp. z o.o. Jagiellońska 69/1 Bydgoszcz Report no.: SRPL21-444-336FE GEP - yes Unpublished	N	Y	Data/study report never submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.3/01	Jörg Semrau	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04983 (field phase) GLP unpublished	N	Y	Data/study report submitted before to Poland	Chemiroł 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
KCP 6.3/02	Dr. Sönke Lakaschus Sabrina Fritzs	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04983 (Analytical phase) GLP unpublished	N	Y	Data/study report submitted before to Poland	Chemiroi Sp. z o.o.
KCP 6.3/03	Jörg Semrau	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04903 (field phase) GLP unpublished	N	Y	Data/study report submitted before to Poland	Chemiroi Sp. z o.o.
KCP 6.3/04	Dr. Sönke Lakaschus Sabrina Fritzs	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04903 (Analytical phase) GLP unpublished	N	Y	Data/study report submitted before to Poland	Chemiroi 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
KCP 6.3/05	Jörg Semrau	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04904 (field phase) GLP unpublished	N	Y	Data/study report submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.3/06	Dr. Sönke Lakaschus Sabrina Fritzsche	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04904 (Analytical phase) GLP unpublished	N	Y	Data/study report submitted before to Poland	Chemiroł Sp. z o.o.
KCP 6.3/07	Jörg Semrau	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04905 (field phase) GLP unpublished	N	Y	Data/study report submitted before to Poland	Chemiroł 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
KCP 6.3/08	Dr. Sönke Lakaschus Sabrina Fritzsche	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04905 (Analytical phase) GLP unpublished	N	Y	Data/study report submitted before to Poland	Chemirolo Sp. z o.o.
KCP 6.3/09	Jörg Semrau	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04906 (field phase) GLP unpublished	N	Y	Data/study report submitted before to Poland	Chemirolo Sp. z o.o.
KCP 6.3/10	Dr. Sönke Lakaschus Sabrina Fritzsche	2018	Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Eurofins, Germany Study no.: S17-04906 (Analytical phase) GLP unpublished	N	Y	Data/study report submitted before to Poland	Chemirolo Sp. z o.o.

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KCP 7.1.1 KCP 7.1.2 KCP 7.1.3 KCP 7.1.4 KCP 7.1.5 KCP 7.1.6	Żero K.	2022	Toxicological classification of product CHR/H/IZOXACYP 250 SC based on calculation method taking into consideration health hazards of constituent substances PUH Chemirol Sp. z o. o. Non GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol Sp. z o.o.
KCP 9.1.3	Spankowski W.	2022	CHR/H/IZOXACYP 250 SC <i>Predicted environmental concentration of isoxaflutole and its metabolites in soil</i> Non-GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 9.2.4	Spankowski W.	2022	CHR/H/IZOXACYP 250 SC <i>Predicted environmental concentration of isoxaflutole and its metabolites in ground water</i> Non-GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 9.2.5	Spankowski W.	2022	CHR/H/IZOXACYP 250 SC <i>Predicted environmental concentration of isoxaflutole and its metabolites in surface water and sediment</i> Non-GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 10.2/1	Nierzędska E.	2021	<i>Daphnia magna</i> , Acute immobilisation test Łukasiewicz Research Network W-50-20 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 10.2/2	Nierzędska E.	2021	<i>Raphidocelis subcapitata</i> , Growth inhibition test Łukasiewicz Research Network W-51-20 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 10.2/3	Nierzędska E.	2021	<i>Lemna gibba</i> , Growth inhibition test	N	Y	Data/study report never sub-	Chemirol

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
			Łukasiewicz Research Network W-52-20 GLP Unpublished			mitted before to Poland	
KCP 10.2/4	Nierzędska E.	2021	<i>Anabaena flos-aquae</i> , Growth inhibition test Łukasiewicz Research Network W-53-20 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 10.3.1/1	Holewik P.	2021	<i>Honeybees (Apis mellifera L.)</i> , Chronic Oral Toxicity Test Łukasiewicz Research Network B-30-21 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 10.3.1/2	Holewik P.	2021	<i>Honeybees (Apis mellifera L.)</i> , Acute Oral Toxicity Test Łukasiewicz Research Network B-31-21 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 10.3.1/3	Holewik P.	2021	<i>Honeybees (Apis mellifera L.)</i> , Acute Contact Toxicity Test Łukasiewicz Research Network B-32-21 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol
KCP 10.3.1/4	A. Wozniak	2022	<i>Honey bee larval toxicity test following repeated exposure of the test item Izoaxaflutole 250 SC (CHR/H/IZOXACYP 250 SC) according to OECD GD 239 ENV/JM/MONO(2016)34</i> Study code: 0038/0060 E SORBOLAB Research Laboratory LLC, Zaniemyska 11 Street, 61-029 Poznań, Poland GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.2/1	Holewik P.	2021	<i>An extended laboratory test for evaluating effects of IZOX AFLUTOLE 250 SC (CHR/H/IZOXACYP 250 SC) on the ladybird beetle, Coccinella septempunctata (L.)</i> Łukasiewicz Research Network B-26-21 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 10.3.2/2	Holewik P.	2021	<i>An extended laboratory test for evaluating the effects of IZOX AFLUTOLE 250 SC (CHR/H/IZOXACYP 250 SC) on the predatory mite, Typhlodromus pyri (Sch.)</i> Łukasiewicz Research Network B-27-21 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 10.3.2/3	Holewik P.	2021	<i>An extended laboratory test for evaluating the effects of IZOX AFLUTOLE 250 SC (CHR/H/IZOXACYP 250 SC) on the parasitic wasp, Aphidius rhopalosiphii</i> Łukasiewicz Research Network B-28-21 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 10.3.2/4	Holewik P.	2021	<i>An extended laboratory test for evaluating the effects of IZOX AFLUTOLE 250 SC (CHR/H/IZOXACYP 250 SC) on the green lacewing, Chrysoperla carnea (Steph.)</i> Łukasiewicz Research Network B-29-21 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 10.4/1	Wróbel A.	2021	<i>IZOX AFLUTOLE 250 SC (CHR/H/IZOXACYP 250 SC) Earthworm Reproduction Test (Eisenia andrei)</i> Łukasiewicz Research Network G-83-20 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.4/2	Arendarczyk A.	2021	<i>IZOXAFLUTOLE 250 SC (CHR/H/IZOXACYP 250 SC)</i> <i>Collembolan (Folsomia candida) Reproduction Test</i> Łukasiewicz Research Network G-84-20 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 10.4/3	Arendarczyk A.	2021	<i>IZOXAFLUTOLE 250 SC (CHR/H/IZOXACYP 250 SC)</i> <i>Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil</i> Łukasiewicz Research Network G-85-20 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 10.5/1	Czarnynoga M.	2021	<i>IZOXAFLUTOLE 250 SC (CHR/H/IZOXACYP 250 SC)</i> <i>Soil Microorganisms: Nitrogen Transformation Test</i> Łukasiewicz Research Network G-86-20 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 10.6/1	Czarnynoga M.	2021	<i>IZOXAFLUTOLE 250 SC (CHR/H/IZOXACYP 250 SC)</i> <i>Terrestrial Plant Test: Vegetative Vigour Test</i> Łukasiewicz Research Network G-87-20 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
KCP 10.6/2	Wróbel A.	2021	<i>IZOXAFLUTOLE 250 SC (CHR/H/IZOXACYP 250 SC)</i> <i>Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test</i> Łukasiewicz Research Network G-88-20 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Chemrol
Data matching of isoxaflutole	Zieliński, J.	2016	RPA 202248 Determination of partition coefficient 1-octanol/water at	N	Y	Data/study report never submitted before to Poland.	Chemrol

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
			three pH values Study no: BF-56/16-02 IPO Warszawa GLP, unpublished				
Data matching of isoxaflutole	Lewandowska, M.	2016	RPA 203328 Determination of partition coefficient 1-octanol/water at three pH values Study no: BF-57/16-02 IPO Warszawa GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Zieliński, J.	2016	RPA 205834 Determination of partition coefficient 1-octanol/water at three pH values Study no: BF-58/16-02 IPO Warszawa GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Flasińska, P.	2016	Isoxaflutole TC Determination of flammability, relative, self-ignition temperature and oxidizing properties Study No.: BC-99/16 GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Buczkowski, D.	2016	Isoxaflutole TC Determination of explosive properties Study No.: BC-17/16 GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Zieliński, J.	2016	RPA 202248 Determination of solubility in water at three pH values Study nu.: BF-56/16-01 GLP, unpublished IPO Warszawa	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Petryka, M.	2016	RPA 202248 Determination of vapour pressure using effusion method with Knudsen cell	N	Y	Data/study report never submitted before to Poland.	Chemirol

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
			Study nu.: BC-82/16 GLP, unpublished IPO Warszawa				
Data matching of isoxaflutole	Sobera-Madej, S.	2016	RPA 202248 Determination of the dissociation constant Study nu.: BF-56/16-03 GLP, unpublished IPO Warszawa	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Petryka, M.	2016	RPA 203328 Determination of vapour pressure using effusion method with Knudsen cell Study nu.: BC-83/16 GLP, unpublished IPO Warszawa	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Sobera-Madej, S.	2016	RPA 203328 Determination of the dissociation constant Study code: BF-57/16-03 GLP, unpublished IPO Warszawa	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Zieliński, J.	2016	RPA 205834 Determination of solubility in water at three pH values Study nu.: BF-58/16-01 GLP, unpublished IPO Warszawa	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Petryka, M.	2016	RPA 205834 Determination of vapour pressure using effusion method with Knudsen cell Study nu.: BC-84/16 GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol

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
			IPO Warszawa				
Data matching of isoxaflutole	Sobera-Madej. S	2016	RPA 205834 Determination of the dissociation constant Study code: BF-58/16-03 GLP, unpublished IPO Warszawa	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Jörg Semrau	2018	Final Report Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Study code: S17-04903 GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Jörg Semrau	2018	Final Report Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Study code: S17-04904 GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Jörg Semrau	2018	Final Report Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Study code: S17-04905 GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Jörg Semrau	2018	Final Report Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017	N	Y	Data/study report never submitted before to Poland.	Chemirol

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
			Study code: S17-04906 GLP, unpublished				
Data matching of isoxaflutole	Jörg Semrau	2018	Final Report Determination of residues of terbuthylazine, mesotrione and isoxaflutole after one application of TERIZ 650 WG in maize at 1 site in Northern Europe 2017 Study code: S17-04983 GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Dr Knop, M.	2019	Development and Validation of an Analytical Method for the Determination of Isoxaflutole and RPA202248 in Different Plant Matrices Study Code S19-04082 Eurofins Agrosience Services EcoChem GmbH GLP/GEP: Yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Imart, C.	2019	Independent Laboratory Validation of Analytical Method for the Determination of Isoxaflutole and RPA 202248 in Foodstuffs of Plant Origin Study Code S19-04084 Eurofins Agrosience Services Chem SAS 75 B Avenue de Pascalet 30310 Vergèze France GLP/GEP: Yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Dr Knop, M.	2019	Final Report Development and Validation of an Analytical Method for the Determination of Isoxaflutole and RPA202248 in Different Animal Matrices Eurofins Agrosience Services EcoChem GmbH Eutinger Str. 24 D-75223 Niefern-Öschelbronn Germany	N	Y	Data/study report never submitted before to Poland.	Chemrol

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
			Study Code: S19-04083 GLP/GEP: Yes Unpublished				
Data matching of isoxaflutole	Imart, C.	2019	Independent Laboratory Validation of Analytical Method for the Determination of Isoxaflutole and RPA 202248 in Foodstuffs of Animal Origin Eurofins Agrosience Services Chem SAS 75 B Avenue de Pascalet 30310 Vergèze France Study Code S19-04085 GLP/GEP: yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Solà J.	2016	[Phenyl-UL-14C]Isoxaflutole: Metabolic Stability and Profiling in Liver Microsomes from Rats and Humans for Inter-species Comparison Envigo Study Number: S57580 GLP/GEP: yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Antosik, J.	2016	Phototoxicity Test of isoxaflutole according to the OECD 432 Guideline (In Vitro 3T3 NRU Phototoxicity Test) Study number: K80/JA/02 Selvita GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Antonik, J.	2016	In vitro evaluation of RPA203328 using the micronucleus assay (MNA) Study number: K81/JA/02 Selvita, GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Antonik, J.	2016	In vitro Mammalian Cell Gene Mutation test (OECD 490) - genotoxicity determination of RPA203328. Study number: K82/JA/02 Selvita	N	Y	Data/study report never submitted before to Poland.	Chemirol

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, unpublished				
Data matching of isoxaflutole	Rooney, P.	2018	Field dissipation assessment and quantification of RPA 202248 and secondary metabolite RPA 203328 residues in soil cores after spray application of RPA 202248 at four EU based field sites Fera Study Number: FR/000490 Fera Science Ltd, UK GLP, unprotected	N	Y	Data/study report never submitted before to Poland.	Chemirool
Data matching of isoxaflutole	van Beinum, W	2018	Normalisation and kinetic analysis to derive field DT50 for RPA 202248 and RPA 203328 Project code: RA0530 Report Number: E2017-46 Supporting Materials: E2017-46-A1 and A2 Enviresearch Limited GLP, unprotected	N	Y	Data/study report never submitted before to Poland.	Chemirool
Data matching of isoxaflutole	Winiarka, K.	2017	RPA 203328 Adsorption – Desorption Using a Batch Equilibrium Method according to the OECD Guideline No. 106 and the EU Method C.18. STUDY CODE: C/14/16 IPO Pszczyna GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirool
Data matching of isoxaflutole	Strack, J.	2017	[phenyl-U-14C] Isoxaflutole: Aerobic Mineralisation in Surface Water – Simulation Biodegradation Project: 96101120 Ibacon GmbH GLP, unprotected	N	Y	Data/study report never submitted before to Poland.	Chemirool
Data matching of isoxaflutole	Fox, M.	2019	Isoxaflutole: Determination of Mysid (Americamysis bahia) acute toxicity under flow through conditions Study number 1037.00302 Scymaris Ltd., Brixham Laboratory, Freshwater Quarry, Brixham, Devon, TQ5 8BA, UK	N	Y	Data/study report never submitted before to Poland.	Chemirool

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, unprotected				
Data matching of isoxaflutole	B.Burden	2021	RPA 202248: Determination of acute toxicity to <i>Americamysis bahia</i> in a semi-static test Study No. 1037.00404 Scymaris Ltd., Brixham Laboratory, Freshwater Quarry, Brixham, Devon, TQ5 8BA, UK GLP: yes unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Dr. Carmen Börschig Dr. Christoph Härtel	2016	Isoxaflutole: Influence to <i>Daphnia magna</i> in a Semi-Static Reproduction Test Project 110421221 ibacon GmbH Arheilger Weg 17 64380 Rossdorf Germany GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Maunder.R.	2019	Isoxaflutole: Chronic toxicity to mysids <i>Americamysis bahia</i> under flow-through conditions Study number 1037.00303 Scymaris Ltd., Brixham Laboratory, Freshwater Quarry, Brixham, Devon, TQ5 8BA, UK GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Bak, P.	2019	Isoxaflutol a.s. <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i>) Growth inhibition test according to the OECD Guideline No. 201 (2006) STUDY CODE: W/27/19, MSc Testing facility: Institute of Industrial Organic Chemistry Branch Psczyna GLP, Unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Konfederek, E	2017	Izoaxaflutole a.s. <i>Anabaena flos-aquae</i> UTEX B 1444 Growth inhibition test according to the OECD Guideline No. 201 (2006) / EU Method C.3. STUDY CODE: W/178/16	N	Y	Data/study report never submitted before to Poland.	Chemrol

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
			IPO Pszczyna GLP, unpublished				
Data matching of isoxaflutole	Bąk, P	2019	Isoxaflutol a.s. Navicula pelliculosa SAG 1050-3 Growth inhibition test according to the OECD Guideline No. 201 (2006), EU Method C.3. STUDY CODE: W/30/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP: yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Turek, T.	2017	CHR/H/TERIZ Water-sediment Myriophyllum spicatum toxicity test According to OECD Guideline No. 239 (2014) STUDY CODE: W/226/17 IPO Warszawa GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Dr. Carmen Börschig Dr. Christoph Härtel	2016	RPA 203328: Toxicity to the Aquatic Plant Lemna gibba in a Static Growth Inhibition Test Project 110411240 IBACON GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Dr. Carmen Börschig Dr. Christoph Härtel	2016	RPA205834: Toxicity to the Aquatic Plant Lemna gibba in a Semi-Static Growth Inhibition Test Project 110441240 ibacon GmbH Arheilger Weg 17 64380 Rossdorf Germany GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Wołany, M	2019	Isoxaflutole a.s. Earthworm Reproduction Test (Eisenia andrei) according to OECD Guideline No. 222 (2016) STUDY CODE: G/20/19	N	Y	Data/study report never submitted before to Poland.	Chemirol

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
			Łukasiewicz Research Network – Institute of Industrial Organic Chemistry Branch Pszczyna GLP/GEP: yes Unpublished				
Data matching of isoxaflutole	Ulf Lührs	2016	RPA 202248: Effects on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil Project 110401022 IBACON, GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Ulf Lührs	2016	RPA 203328: Effects on Reproduction and Growth of Earthworms Eisenia fetida in Artificial Soil Project 110411022 IBACON, GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Lührs, U	2016	Isoxaflutole 98% TC: Effects on Reproduction of the Collembola Folsomia candida in Artificial Soil with 5% Peat Project 110421016 IBACON, GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Lührs, U	2016	Isoxaflutole 98% TC: Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil with 5% Peat Project 110421089	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Lührs, U	2016	RPA202248: Effects on Reproduction of the Collembola Folsomia candida in Artificial Soil with 5% Peat Project 110401016 IBACON, GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of isoxaflutole	Lührs, U.	2016	RPA202248 Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil with 5% Peat Project 110401089 IBACON GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemrol
Data matching of	Lührs, U.	2016	RPA203328: Effects on Reproduction of the Collembola	N	Y	Data/study report never sub-	Chemrol

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
isoxaflutole			Folsomia candida in Artificial Soil with 5% Peat Project 110411016 IBACON, GLP, unpublished			mitted before to Poland.	
Data matching of isoxaflutole	Lührs, U.	2016	RPA203328 Effects on Reproduction of the Predatory Mite Hypoaspis aculeifer in Artificial Soil with 5% Peat Project 110411089 IBACON GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Dr. Ute Hammesfahr	2016	RPA 202248: Effects on the Activity of the Soil microflora in the Laboratory (Nitrogen Transformation) Project 110401080 IBACON, GLP, unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol
Data matching of isoxaflutole	Gierbuszewska, A.	2019	Isoxaflutole a.s. Activated Sludge, Respiration Inhibition Test according to the OECD Guideline No. 209 (2010) / EU Method C.11. STUDY CODE: G/21/19 Łukasiewicz Research Network – Institute of Industrial Organic Chemistry, Branch Pszczyna GLP/GEP: yes Unpublished	N	Y	Data/study report never submitted before to Poland.	Chemirol

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.1.2/01	Manley, J. D.	1995	Analytical method for the determination of residues of RPA 201772, RPA 202248 and RPA 203328 in maize forage, grain and fodder Rhone-Poulenc	N	N	-	Bayer Crop-

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	Justifica- tion if data protection is claimed	Owner
			Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C021001, Edition Number: M-210419-01-1 Date: 1995-10-24 GLP/GEP: yes, unpublished ...also filed: KCA 4.2 /05				Science
KCA 5.1.2/02	Austin, D. J.; Man- ley, J. D.	1995	Herbicides: RPA201772: The evaluation of alternative procedures to diazo-methane for the preparation of esters of RPA203328 for the "Analytical method for the determination of residues of RPA201772, RPA202248 and RPA203328 in maize grain an Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000352, Report includes Trial Nos.: P94/110 Edition Number: M-158450-01-1 Date: 1995-04-28 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 5.1.2/03	Schuster, L.L.,	1995 a	PR Notice 88-5 Enforcement Method Confirmation for RPA 201772 and its Metabolites RPA 202248 and RPA 203328 in Corn Grain Generated by: ABC Laboratories, Pan-Ag Division, Madera, California, USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94454, Docmap n° 44663 Date of report: February 23, 1995	N	N	-	Bayer Crop- Science
KCA 5.1.2/04	Guillet, M., Venet, C. & Simonin, B.,	1995	Isoxaflutole and Metabolites: Analytical Method for the Determination of Residues in Soil. Generated by: Rhône-Poulenc Secteur Agro, Lyon, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: AR 106-94 (E), Docmap n° 437490, Date of report: February 2, 1995.	N	N	-	Bayer Crop- Science
KCA 5.1.2/05	Schuster, L.L.,	1995	Method Confirmation for RPA 201772 and its Metabolites RPA 202248, RPA 203328 and RPA 205834 in Soil. Generated by: ABC Laboratories, Pan-Ag Division, Madera, California, USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: EC-95-305 Date of report: November 7, 1995	N	N	-	Bayer Crop- Science
KCA 5.1.2/06	Plaisance, R.S., 1995	1995	Validation of Method of Analysis for Isoxaflutole and its Metabolites in/on Agricultural Soil. Generated by: Rhône-Poulenc Ag, Co., USA. Submitted by: Rhône-Poulenc Agro,	N	N	-	Bayer Crop- Science

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			France. Report/file N°: EC-95-299 Date of report: November 6, 1995				
KCP 5.1.2/07	Corgier, M. and Turier, G.,	1995	Analytical Method for the Determination of Isoxaflutole in Air. Generated by: Rhône-Poulenc Agro, France. Submitted by: Rhône-Poulenc Agro, France. Report/file N°: 94-115 Docmap 438832 Date of report: June 15, 1995	N	N	-	Bayer Crop-Science
KCP 5.2/1	Guillet, M., Venet, C. & Simonin, B.,	1995	Isoxaflutole and Metabolites: Analytical Method for the Determination of Residues in Soil. Generated by: Rhône-Poulenc Secteur Agro, Lyon, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: AR 106-94 (E), Docmap n° 437490, Date of report: February 2, 1995.	N	N	-	Bayer Crop-Science
KCP 5.2/2	Schuster, L.L.,	1995	Method Confirmation for RPA 201772 and its Metabolites RPA 202248, RPA 203328 and RPA 205834 in Soil. Generated by: ABC Laboratories, Pan-Ag Division, Madera, California, USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: EC-95-305 Date of report: November 7, 1995	N	N	-	Bayer Crop-Science
KCP 5.2/3	Plaisance, R.S., 1995	1995	Validation of Method of Analysis for Isoxaflutole and its Metabolites in/on Agricultural Soil. Generated by: Rhône-Poulenc Ag, Co., USA. Submitted by: Rhône-Poulenc Agro, France. Report/file N°: EC-95-299 Date of report: November 6, 1995	N	N	-	Bayer Crop-Science
KCP 5.2/4	Corgier, M. and Turier, G.,	1995	Analytical Method for the Determination of Isoxaflutole in Air. Generated by: Rhône-Poulenc Agro, France. Submitted by: Rhône-Poulenc Agro, France. Report/file N°: 94-115 Docmap 438832 Date of report: June 15, 1995	N	N	-	Bayer Crop-Science
KCP 5.2/5	Guillet, M. , Diot, R.	1995	Isoxaflutole and/or Metabolites: Analytical Method for the Determination of Residues in Animal Products	N	N	-	Bayer

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	& Le Gren, I.,	b	Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: AR 109-95 (E) Date of report: April 12, 1995				Crop- Science
KCP 5.2/6	Guillet, M. , & Le Gren, I.,	1995 d	Isoxaflutole and/or Metabolites: Analytical Method for the Determination of Residues in Animal Products Complementary Report Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 9515587 Date of report: May 23, 1995	N	N	-	Bayer Crop- Science
KCP 5.2/7	Guillet, M. , Diot, R. & Le Gren, I.,	1995 b	Isoxaflutole and/or Metabolites: Analytical Method for the Determination of Residues in Animal Products Complementary Report n°:2 Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 9516279 Date of report: September 20, 1995	N	N	-	Bayer Crop- Science
KCP 5.2/8	Hunt, T.W. and Lopes, A.,	1995	Isoxaflutole - Validation of Method of Analysis for Isoxaflutole and its Metabolites in Animal Tissues. Generated by: Rhône-Poulenc Ag Co., USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: EC-95-313 Date of report: December 28, 1995	N	N	-	Bayer Crop- Science
KCP 5.2/9	Shaffer, S.	1995	Independent Laboratory Validation of the Rhône-Poulenc Methods entitled, "Method of Analysis for the determination of Isoxaflutole and its Metabolites (RPA 203328, RPA 202248 and RPA 205834 in Milk" and "Method of Determination for Isoxaflutole and its Metabolite (RPA 202248) in/on Bovine and Poultry Tissues" Generated by: Horizon Laboratories Inc. Columbia, Missouri, USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: EC-95-233	N	N	-	Bayer Crop- Science

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			Date of report: December 22, 1995				
KCA 5.8.1 /3	N/D		RPA202248 - Oral limit test in the rat [REDACTED] [REDACTED] GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCA 5.8.1 /4	N/Dxxxxxx		Salmonella typhimurium reverse mutation assay (Ames test) RPA202248 [REDACTED] GLP/GEP: yes, unpublished	N	N	-	
KCA 5.8.1 /5	N/D		RPA203328 - Oral limit test in the rat , [REDACTED] [REDACTED] GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCA 5.8.1 /6	N/D		28-day toxicity study in the rat by dietary administration RPA203328 (a metabolite of RPA201772) [REDACTED] [REDACTED] GLP/GEP: yes, unpublished	Y	N	-	
KCA 5.8.1 /7	N/D		Reverse mutation assay (Ames test) Salmonella typhimurium RPA203328 , [REDACTED] GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 5.8.1 /8	N/D		RPA 203328 - Exploratory 14-day toxicity study in the rat by gavage , [REDACTED] Date: 1994-10-12 GLP/GEP: no, unpublished	Y	N	-	Bayer Crop- Science
KCA 5.8.1 /9	N/D		RPA 203328: 90-Day Toxicity Study in the Rat by Dietary Administration , [REDACTED] Date: 1998-09-23 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCA 5.8.1 /10	N/D		Mutagenicity test on RPA203328 - Measuring chromosomal aberrations in Chinese hamster ovary (CHO) cells , [REDACTED] Date: 1998-04-07 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCA 5.8.1 /11	N/D		Mutagenicity test on RPA203328 in the CHO/HGPRT forward mutation assay with duplicate cultures and a confirmatory assay , [REDACTED] GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCP 6.1/01	Nandihalli, U. B.	1996	Freezer storage stability of RPA201772 in field corn samples Corning Hazleton, Inc., Madison, WI, USA	N	N	-	Bayer Crop-

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	Justifica- tion if data protection is claimed	Owner
			Bayer CropScience, Report No.: R016771, Edition Number: M-192327-01-1 Date: 1996-11-07 GLP/GEP: yes, unpublished				Science
KCP 6.2.1/01	Hampton, R. E.; Pettaway, J.	1995	14C-RPA201772: Metabolic fate and distribution in corn (Zea mays L.) - (171-4 Nature of residue - Plants) A&L Great Lakes Laboratories, Fort Wayne, IN, USA BCS, Report No.: R002551, Edition Number: M-162883-01-1 Date: 1995-02-13 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCP 6.2.2/01		1995	(14C)-RPA201772: Absorption, distribution, metabolism and excretion following repeated oral administration to the laying hen Report No.: M-170844-01-2, Report includes Trial Nos.: 198/77-1011 Edition Number: M-170844-01-2 Date: 1995-11-30 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCP 6.2.2/02		1995	(14C)-RPA201772: Absorption, distribution, metabolism and excretion following repeated oral administration to the dairy goat Report No.: R004900, Report includes Trial Nos.: 198/78-1011 Edition Number: M-166744-01-1 Date: 1995-12-27 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCP 6.3/01	Muller, M. A.	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Maize (Grain)	N	N	-	Bayer Crop- Science

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			Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-562 Date of report: November 7, 1995				
KCP 6.3/02	Muller, M.A.,	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Maize (Silage) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-563 Date of report: November 7, 1995	N	N	-	Bayer Crop- Science
KCP 6.3/03	Muller, M. A.	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Sweet Maize (Cob) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-564 Date of report: October 26, 1995	N	N	-	Bayer Crop- Science
KCP 6.3/04	Muller, M.A.,	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Maize, Decline Study Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-565 Date of report: October 24, 1995	N	N	-	Bayer Crop- Science
KCP 6.3/05	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Germany 1994, Residues in Maize, Decline Study, Residues in Maize Processing Products Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-605 Date of report: January 5, 1996	N	N	-	Bayer Crop- Science

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KCP 6.3/06	Muller, M. A.	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Spain 1994, Residues in Maize (Grain, Straw) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-658 Date of report: October 18, 1995	N	N	-	Bayer Crop- Science
KCP 6.3/07	Muller, M.A.,	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Italy 1994, Residues in Maize (Silage, Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-669 Date of report: October 18, 1995	N	N	-	Bayer Crop- Science
KCP 6.3/08	Muller, M. A.	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Greece 1994, Residues in Maize (Silage, Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-680 Date of report: October 18, 1995, unpublished	N	N	-	Bayer Crop- Science
KCP 6.3/09	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1995, Residues in Maize , Decline Study Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-531 Date of report: January 5, 1996	N	N	-	Bayer Crop- Science
KCP 6.3/10	Muller, M. A.	1996	RPA201772 or Isoxaflutole and its metabolites (RPA202248 and RPA203328) formulation EXP31130A (wg) trials italy 1994 residues in maize (silage, grain) Rhône-Poulenc Agro, Lyon, France	N	N	-	Bayer Crop- Science

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			Bayer CropScience, Report No.: C027228, Report includes Trial Nos.: 94-669 Edition Number: M-212937-01-1 Date: 1995-10-18 GLP/GEP: yes, unpublished				
KCP 6.3/11	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Spain 1995, Residues in Sweet Maize (Cob) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-711 Date of report: January 5, 1996	N	N	-	Bayer Crop- Science
KCP 6.3/12	Muller, M.A.,	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Italy 1995, Residues in Maize (Silage and Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-756 Date of report: January 5, 1996	N	N	-	Bayer Crop- Science
KCP 6.3/13	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Spain 1995, Residues in Maize , Decline Study Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-757 Date of report: January 4, 1996	N	N	-	Bayer Crop- Science
KCP 6.3/14	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Germany 1995, Residues in Maize , Decline Study	N	N	-	Bayer Crop- 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 protec- tion claimed Y/N	Justifica- tion if data protection is claimed	Owner
			Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-757 Date of report: January 4, 1996				
KCP 6.3/15	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA 202248 and RPA 203328), Aclonifen, Formulation EXP 31325A (SC), Trial Italy 1995, Residues in Maize (Silage and Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-769 Date of report: January 5, 1996	N	N	-	Bayer Crop- Science
KCP 6.3/16	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Aclonifen, Formulation EXP 31325A (SC), Trial France 1995, Residues in Maize (Silage and Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-532 Date of report: January 8, 1996	N	N	-	Bayer Crop- Science
KCP 6.3/17	Muller, M.A.,	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Atrazine, Formulation EXP 31330A (SC), Trial France 1995, Residues in Maize (Silage and Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 95-533 Date of report: January 12, 1996	N	N	-	Bayer Crop- Science
KCP 6.3/18	Muller, M. A.	1996	RPA201772 or Isoxaflutole and its metabolites (RPA202248 and RPA203328) formulation EXP31130A (WG) trials Germany 1995 residues in maize decline study Rhône-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C027242, Report includes Trial Nos.: 95-684	N	N	-	Bayer Crop- 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 protec- tion claimed Y/N	Justifica- tion if data protection is claimed	Owner
			Edition Number: M-212965-01-1 Date: 1996-01-18 GLP/GEP: yes, unpublished				
KCP 6.3/19	Cappy, J.J.,	1995	EXP 30953B - Field Corn / Magnitude of Residues in Processing Fractions Generated by: Rhône-Poulenc Ag. Co., USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: US 93703R Date of report: February 24, 1995	N	N	-	Bayer Crop- Science
KCP 6.3/20	Muller, M. A.	1996	RPA201772 or isoxaflutole and its metabolites (RPA202248 and RPA203328) - ACLONIFEN - Formulation EXP31325A (SC) - Trials Italy 1995 - Residues in maize (silage and grain) Rhône-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: R007334, Report includes Trial Nos.: 95-769 Edition Number: M-174697-01-1 GLP/GEP: no, unpublished	N	N	-	Bayer Crop- Science
KCP 6.4/01	Tew, E.L.,	1995	Isoxaflutole: Magnitude of Residues in Milk and Tissues of Lactating Dairy Cows Generated by: Southwest Bio-Labs, Las Cruces, NM, USA. & Rhône-Poulenc Ag. Co., USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: US95704R Date of report: December 27, 1995	N	N	-	Bayer Crop- Science
KCP 6.4/02	Tew, E.L.,	1995	Isoxaflutole: Magnitude of Residues in Tissues and Eggs of Laying Hens Generated by: Southwest Bio-Labs, Las Cruces, NM, USA. & Rhône-Poulenc Ag. Co., USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: US95705R Date of report: December 28, 1995	N	N	-	Bayer Crop- 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 protec- tion claimed Y/N	Justifica- tion if data protection is claimed	Owner
KCP 6.5/01	Cappy, J. J.	1995	EXP 30953B/ Field corn / Magnitude of residue in processing fractions (US93703R) Heartland Technologies, Inc., Indianapolis, Indiana, USA Bayer CropScience, Report No.: C026230, Edition Number: M-211010-01-1 Date: 1995-02-23 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCP 6.6.1/01	Hampton, R. E.; Pettaway, J.	1995	14C-RPA 201772 - Accumulation Study on Confined Rotational Crops Generated by: Rhône-Poulenc Ag. Co., USA Submitted by: Rhône-Poulenc Agro, France Report/file N°: EC-93-242 Date of report: December 28, 1995	N	N	-	Bayer Crop- Science
KCP 6.6.1/02	Hampton, R. E.	1996	Supplemental report: 14C-RPA201772: Accumulation study on confined rotational crops - (MRID no. 43904839) Rhône-Poulenc Ag Company, RTP, NC, USA Bayer CropScience, Report No.: R016770, Edition Number: M-192325-01-1 EPA MRID No.: 43904839 Date: 1996-11-27 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCP 6.1/01	Nandihalli, U. B.	1996	Freezer storage stability of RPA201772 in field corn samples Corning Hazleton, Inc., Madison, WI, USA Bayer CropScience, Report No.: R016771, Edition Number: M-192327-01-1 Date: 1996-11-07 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCP 6.2.1/01	Hampton, R. E.; Pettaway, J.	1995	14C-RPA201772: Metabolic fate and distribution in corn (Zea mays L.) - (171-4 Nature of residue - Plants) A&L Great Lakes Laboratories, Fort Wayne, IN, USA BCS,	N	N	-	Bayer Crop- 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 protec- tion claimed Y/N	Justifica- tion if data protection is claimed	Owner
			Report No.: R002551, Edition Number: M-162883-01-1 Date: 1995-02-13 GLP/GEP: yes, unpublished				
KCP 6.2.2/01	Lappin, G.J.,	1995	(14C)-RPA201772: Absorption, distribution, metabolism and excretion following repeated oral administration to the laying hen Report No.: M-170844-01-2, Report includes Trial Nos.: 198/77-1011 Edition Number: M-170844-01-2 Date: 1995-11-30 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCP 6.2.2/02	Lappin, G.J.,	1995	(14C)-RPA201772: Absorption, distribution, metabolism and excretion following repeated oral administration to the dairy goat Report No.: R004900, Report includes Trial Nos.: 198/78-1011 Edition Number: M-166744-01-1 Date: 1995-12-27 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCP 6.3/01	Muller, M. A.	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Maize (Grain) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-562 Date of report: November 7, 1995	N	N	-	Bayer Crop- Science
KCP 6.3/02	Muller, M.A.,	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Maize (Silage) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-563	N	N	-	Bayer Crop- 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 protec- tion claimed Y/N	Justifica- tion if data protection is claimed	Owner
			Date of report: November 7, 1995				
KCP 6.3/03	Muller, M. A.	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Sweet Maize (Cob) Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-564 Date of report: October 26, 1995	N	N	-	Bayer Crop- Science
KCP 6.3/04	Muller, M.A.,	1995	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial France 1994, Residues in Maize, Decline Study Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-565 Date of report: October 24, 1995	N	N	-	Bayer Crop- Science
KCP 6.3/05	Muller, M. A.	1996	RPA 201772 or Isoxaflutole and its Metabolites (RPA202248 and RPA 203328), Formulation EXP 31130A (WG), Trial Germany 1994, Residues in Maize, Decline Study, Residues in Maize Processing Products Generated by: Rhône-Poulenc Agro, France Submitted by: Rhône-Poulenc Agro, France Report/file N°: 94-605 Date of report: January 5, 1996	N	N	-	Bayer Crop- Science
KCA 7.1.1.1 /01	Ferreira, E. M.; Jones, M. K.; New- by, S. E.	1994	RPA201772: Aerobic soil metabolism Rhone-Poulenc Agriculture Ltd., On- gar, Essex, United Kingdom BCS, Report No.: R000347, Edition Number: M-158435-01-1 Date: 1994-10-13 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.1.1 /02	Burr, C. M.	1995	Herbicides: RPA 201772 Route of degradation (aerobic metabolism) in one soil (interim report) Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C022444, Edition Number: M- 213110-01-1 Date: 1995-12-18 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.1.1 /03	Burr, C. M.	1996	Herbicides: Isoxaflutole Route of Degradation (Aerobic Metabolism) in one Soil Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer	N	N	-	Bayer Crop-

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	Justifica- tion if data protection is claimed	Owner
			CropScience, Report No.: B003826, Edition Number: M-240821-01-1 EPA MRID No.: 45658804 Date: 1996-08-12 GLP/GEP: yes, unpublished				Science
KCA 7.1.1.1 /04	Ferreira, E. M.; Bul- lus, C. M.; Jones, M. K.; Simmonds, M. B.	1996	RPA 201772: Rate of Degradation under Aerobic Conditions in Three Soil Types Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: B003827, Edition Number: M-240822-01-1 EPA MRID No.: 45658805 Date: 1996-01-10 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.1.1 /05	Hardy, I. A. J.	2001	Isoxaflutole: Kinetic modelling analysis of a European terrestrial field soil dissipation study Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C015653, Edition Number: M-200916-01-1 EPA MRID No.: 45658806 Date: 2001-12-04 GLP/GEP: no, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.1.1 /06	Gatzweiler, E. W.	1996	RPA 201772: terrestrial field soil dissipation study Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C034014, Report includes Trial Nos.: AR53-94 Edition Number: M-234225-01-1 Date: 1996-02-14 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.1.1 /07	Heinemann, O.	2012	[Cyclopropyl-1-14C]RPA 202248:: Aerobic degradation/metabolism in one European soil Bayer CropScience, Report No.: MEF-11/486, Edition Number: M-427583-01-1 Date: 2012-03-12 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.1.2/01	Burr C. M.; Jones, M. K.; Newby, S. E.	1995	RPA201772 Anaerobic Aquatic Metabolism Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom BCS, Report No.: R016760, Edition Number: M-192288-01-1 Date: 1995-01-30 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.1.3 /01	Ferreira, E. M.	1994	RPA201772 - Soil photolysis Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom BCS, Report No.: R000311, Edition Number: M-158351-01-1 Date: 1994-02-04 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.2 /01	Hardy, I. A. J.	2001	Isoxaflutole: Kinetic modelling analysis of a European terrestrial field soil dissipation study Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C015653, Edition Number: M-200916-01-1 EPA MRID No.: 45658806 Date: 2001-12-04 GLP/GEP: no, unpublished	N	N	-	
KCA 7.1.2 /02	Gatzweiler, E. W.	1996	RPA 201772: terrestrial field soil dissipation study Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C034014, Report includes Trial Nos.: AR53-94 Edition Number: M-234225-01-1 Date: 1996-02-14 GLP/GEP: yes, unpublished	N	N	-	

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	Justifica- tion if data protection is claimed	Owner
KCA 7.1.2.1.1 /01	Ferreira, E. M.; Jones, M. K.; New- by, S. E.	1994	RPA201772: Aerobic soil metabolism Rhone-Poulenc Agriculture Ltd., On- gar, Essex, United Kingdom BCS, Report No.: R000347, Edition Number: M-158435-01-1 Date: 1994-10-13 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.1.1 /02	Burr C. M.	1995	Herbicides: RPA 201772 Route of degradation (aerobic metabolism) in one soil (interim report) Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C022444, Edition Number: M- 213110-01-1 Date: 1995-12-18 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.1.1 /03	Burr, C. M.	1996	Herbicides: Isoxaflutole Route of Degradation (Aerobic Metabolism) in one Soil Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: B003826, Edition Number: M-240821-01-1 EPA MRID No.: 45658804 Date: 1996-08-12 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.1.1 /04	Ferreira, E. M.; Bul- lus, C. M.; Jones, M. K.; Simmonds, M. B.	1996	RPA 201772: Rate of Degradation under Aerobic Conditions in Three Soil Types Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: B003827, Edition Number: M-240822-01-1 EPA MRID No.: 45658805 Date: 1996-01-10 GLP/GEP: yes, unpublishes	N	N	-	
KCA 7.1.2.1.1/0 5	Ferreira, E. M.	1996	RPA 201772: Rate of degradation under aerobic conditions in one soil at 10 degrees C Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C022445, Edition Number: M-213113-01-1 Date: 1996-01-24 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.1.1/0 6	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of aerobic soil degradation study data to derive trigger endpoints Battelle UK Ltd., Ongar, Essex, United King- dom Bayer CropScience, Report No.: VC/13/007C, Edition Number: M- 464601-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	N	-	
KCA 7.1.2.1.1/0 7	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of aerobic soil degradation study data to derive modelling endpoints Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/13/007C, Edition Number: M- 464601-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	N	-	
KCA 7.1.2.1.2/0 1	Ferreira, E. M.; Jones, M. K.; New- by, S. E.	1994	RPA201772: Aerobic soil metabolism Rhone-Poulenc Agriculture Ltd., On- gar, Essex, United Kingdom BCS, Report No.: R000347, Edition Number: M-158435-01-1 Date: 1994-10-13 GLP/GEP: yes, unpublished	N	N	-	
KCA	Burr, C. M.	1995	Herbicides: RPA 201772 Route of degradation (aerobic metabolism) in one	N	N	-	

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	Justifica- tion if data protection is claimed	Owner
7.1.2.1.2/0 2			soil (interim report) Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C022444, Edition Number: M-213110-01-1 Date: 1995-12-18 GLP/GEP: yes, unpublished				
KCA 7.1.2.1.2/0 3	Burr, C. M.	1996	Herbicides: Isoxaflutole Route of Degradation (Aerobic Metabolism) in one Soil Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: B003826, Edition Number: M-240821-01-1 EPA MRID No.: 45658804 Date: 1996-08-12 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.1.2/0 4	Ferreira, E. M.; Bul- lus, C. M.; Jones, M. K.; Simmonds, M. B.	1996	RPA 201772: Rate of Degradation under Aerobic Conditions in Three Soil Types Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: B003827, Edition Number: M-240822-01-1 EPA MRID No.: 45658805 Date: 1996-01-10 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.1.2/0 5	Ferreira, E. M	1996	RPA 201772: Rate of degradation under aerobic conditions in one soil at 10 degrees C Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C022445, Edition Number: M-213113-01-1 Date: 1996-01-24 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.1.2/0 6	Heinemann, O.	2012	[Cyclopropyl-1-14C]RPA 202248:: Aerobic degradation/metabolism in one European soil Bayer CropScience, Report No.: MEF-11/486, Edition Number: M-427583-01-1 Date: 2012-03-12 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.1.2/0 7	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of aerobic soil degradation study data to derive trigger endpoints Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/13/007C, Edition Number: M-464601-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	N	-	
KCA 7.1.2.1.2/0 8	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of aerobic soil degradation study data to derive modelling endpoints Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/13/007C, Edition Number: M-464601-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	N	-	
KCA 7.1.2.1.3 /01	Burr C. M.; Jones, M. K.; Newby, S. E.	1995	RPA201772 Anaerobic Aquatic Metabolism Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom BCS, Report No.: R016760, Edition Number: M-192288-01-1 Date: 1995-01-30 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.1.4	Burr C. M.; Jones, M. K.; Newby, S. E.	1995	RPA201772 Anaerobic Aquatic Metabolism Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom BCS, Report No.: R016760, Edition Number:	N	N	-	

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	Justifica- tion if data protection is claimed	Owner
/01			M-192288-01-1 Date: 1995-01-30 GLP/GEP: yes, unpublished				
KCA 7.1.2.2.1/0 1	Gatzweiler, E.W.	1996	RPA 201772: terrestrial field soil dissipation study Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C034014, Report includes Trial Nos.: AR53-94 Edition Number: M-234225-01-1 Date: 1996-02-14 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.2.1/0 2	Gatzweiler, E.W.	1996	RPA 201772: terrestrial field soil dissipation study on four European soils Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: R000410, Report includes Trial Nos.: P94/009 Edition Number: M-158573-01-1 GLP/GEP: no, unpublished	N	N	-	
KCA 7.1.2.2.1/0 3	Heinemann, O.	2012	Determination of the residues of AE 0540092 in/on soil after spraying of AE 0540092 WP 20 in the field in Germany, United Kindom, France (North), Italy and Spain Bayer CropScience, Report No.: 10-2702, Report includes Trial Nos.: 10-2702-01 10-2702-02 10-2702-03 10-2702-04 10-2702-05 10-2702-06 Edition Number: M-428564-01-1 Date: 2012-03-19 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.2.1/0 4	Kieken, J. L.	1997	Storage stability in soils from the European terrestrial field soil dissipation isoxaflutole and metabolites study P94/009 Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C034021, Report includes Trial Nos.: 95-85 Edition Number: M-234239-01-1 Date: 1997-06-17 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.2.2.1/0 5	Hardy, I. A. J.	2013	Kinetic modelling analysis of AE 0540092 and AE B197555 from a field soil residue study conducted in Europe (Normalisation to 20degree and pF2) Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/13/007A, Edition Number: M-464592-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	N	-	
KCA 7.1.2.2.1/0 6	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling endpoint summary Battelle UK Ltd., Chelmsford, United Kingdom Bayer CropScience, Report No.: VC/13/007J, Edition Number: M-464899-01-1 Date: 2013-09-18 GLP/GEP: no, unpublished	N	N	-	
KCA 7.1.3.1.1 /01	Lowden, P.; Cooper, I.; Simmonds, M.; Burr, C. M.; Newby,	1993	[14C]-RPA 201722: Adsorption/desorption to and from four soils and an aquatic sediment - Addendum report Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: M-065963-03-1,	N	N	-	

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	Justifica- tion if data protection is claimed	Owner
	S. E.		Edition Number: M-065963-03-1 Date: 1993-11-25 ...Amended: 2004-04-08 GLP/GEP: yes, unpublished				
KCA 7.1.3.1.1/0 2	Burr C. M.; Newby, S. E.	1993	RPA 201772: Adsorption / desorption to and from four soils and an aquatic sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000307, Edition Number: M-158343-01-1 Date: 1993-11-25 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.3.1.1 /03	Burr, C. M.	1996	14C)-RPA202248: Adsorption / desorption to and from four soils and an aquatic sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Report No.: R016762, Edition Number: M-192293-01-1 Date: 1996-07-17 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.3.1.2 /01	Lowden, P.; Cooper, I.; Simmonds, M.; Burr, C. M.	1995	[14C]-RPA 202248: Adsorption/desorption to and from four soils - Addendum report Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom BCS, Report No.: CX/03/070A, Edition Number: M-066355-03-1 Date: 1995-11-20 ...Amended: 2004-04-08 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.3.1.2 /02	Burr, C. M.	1995	RPA202248: Adsorption / desorption to and from four soils Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Report No.: R016761, Edition Number: M-192291-01-1 Date: 1995-11-20 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.3.1.2 /03	Burr, C. M.	1996	(14C)-RPA202248: Adsorption / desorption to and from four soils and an aquatic sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Report No.: R016762, Edition Number: M-192293-01-1 Date: 1996-07-17 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.3.1.2 /04	Burr, C. M. Burrs, C. M.	1996	RPA 203328: Adsorption/desorption to and from four soils Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C025651, Edition Number: M-209743-02-1 Date: 1996-01-02 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.3.1.2 /05	Burr, C. M.	1996	[14C]-RPA203328: Adsorption / desorption to and from four soils and a sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000447, Report includes Trial Nos.: 11487 Edition Number: M-158651-01-1 Date: 1996-07-30 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.3.1.2	Lowden, P.; Cooper, I.; Simmonds, M.;	1996	[14C]-RPA 202248: Adsorption/desorption to and from four soils and an aquatic sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United	N	N	-	

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/06	Burr, C. M.		Kingdom Bayer CropScience, Report No.: 11486, Edition Number: M-066483-01-1 Date: 1996-07-17 GLP/GEP: yes, unpublished				
KCA 7.1.3.1.2 /07	Burr, C. M.	1996	RPA 203328: Adsorption/desorption to and from four soils Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Report No.: C026341, Edition Number: M-211226-01-1 Date: 1996-01-02 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.3.1.2 /08	Hein, H.; Moendel, M.	2012	[cyclopropyl-1-14C] AE 0540092: Adsorption/desorption in five different soils RLP AgroScience GmbH, Neustadt a. d. Weinstraße, Germany Bayer CropScience, Report No.: AS200, Edition Number: M-429399-01-1 Date: 2012-03-14 GLP/GEP: yes, unpublished	N	N	-	
KCA 7.1.3.1.2 /09	Mills, E. A. M.; Simmonds, M. B.	2004	(14C)-RPA 203328: Adsorption / desorption in five soils Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C040534, Edition Number: M-229091-01-1 EPA MRID No.: 46801704 Date: 2004-04-06 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.4 /01	Gatzweiler, E. W.	1996	Isoxaflutole: Computer simulation of the behaviour in soil using the PELMO 2.01 model Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000415, Edition Number: M-158583-01-1 Date: 1996-01-24 GLP/GEP: no, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.4 /02	Gatzweiler, E. W.	1996	RPA 202248: Computer simulation of the behaviour in soil using the PELMO 2.01 model Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000413, Edition Number: M-158581-01-1 Date: 1996-01-24 GLP/GEP: no, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.4 /03	Hardy, I. A. J.	2001	Isoxaflutole: Leaching risk assessment for isoxaflutole and two metabolites using the European FOCUS groundwater scenarios (AE B197278, AE 0540092, AE B197555) Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: MO-04-004596, Edition Number: M-066960-01-1 Date: 2001-09-14 GLP/GEP: no, unpublished	N	N	-	Bayer Crop- Science
KCA 7.1.4.1.1/0 1	Newby, S. E.; God- ward, P. J.; Jones, M. K.	1995	RPA 201772: Aged leaching study in four soils and a sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000361, Edition Number: M-158471-01-1 Date: 1995-01-10 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA	Corgier, M. M.; Rob-	1994	Hydrolysis 14C-RPA201772 Rhone-Poulenc Agro, Lyon, France Bayer	N	N	-	Bayer

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7.2.1.1 /01	in, J. M.; Plewa, A. P.		CropScience, Report No.: R002384, Report includes Trial Nos.: 93-180 Edition Number: M-162558-01-1 Date: 1994-05-02 GLP/GEP: yes, unpublished				Crop- Science
KCA 7.2.1.2 /01	Corgier, M. M.; Plewa, A. P.	1995	Photodegradation in water 14C RPA201772 (isoxaflutole) Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: R002507, Report includes Trial Nos.: 94-11 Edition Number: M-162794-01-1 Date: 1995-01-13 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.2.1.2 /02	Cousin, J. A.	1993	Amendment No. 1 - RPA201772 active ingredient - Physical and chemical characteristics - Part E: Stability Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: R002181, Report includes Trial Nos.: 93-129 R&D/CRLD/AN/9516351 Edition Number: M-162149-02-1 Date: 1993-11-15 ...Amended: 1993-11-15 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.2.1.2 /03	Roohi, A.; Caine, J.	2002	Photolysis in distilled water RPA202248 Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Report No.: C027919, Report includes Trial Nos.: 36662 CX/02/066 Edition Number: M-214288-01-1 Date: 2002-12-11 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.2.2.1 /01	Desmares Koopmans, M. J. E.	1996	Determination of ready biodegradability: Carbon dioxide (CO2) evolution test (modified Sturm test) with isoxaflutole Notox B.V., 's-Hertogenbosch, Netherlands Bayer CropScience, Report No.: C026345, Edition Number: M-211235-01-1 Date: 1996-01-23 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.2.2.1 /02	Desmares Koopmans, M. J. E.	1996	Determination of 'ready' biodegradability carbon dioxide (CO2) - Evolution test (modified Sturm test) with RPA201772 Notox B.V., 's-Hertogenbosch, Netherlands Bayer CropScience, Report No.: R002745, Report includes Trial Nos.: 58077 96-22 Edition Number: M-163261-01-1 Date: 1996-01-23 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.2.2.2 /01	Walther, D.	2013	[14C] Isoxaflutole: Aerobic mineralization in surface water Harlan Laboratories Ltd., Itingen, Switzerland Bayer CropScience, Report No.: D62847, Edition Number: M-459354-02-1 Date: 2013-06-26 ...Amended: 2013-07-02 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.2.2.3 /01	Ayliffe, J. M.; Newby, S. E.	1995	RPA 201772: Degradation and retention in two water / sediment systems Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000377, Edition Number: M-158508-01-1 Date:	N	N	-	Bayer Crop- Science

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			1995-05-04 GLP/GEP: yes, unpublished				
KCA 7.2.2.3 /02	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of water sediment degradation study data to derive total system DT50 values Battelle UK Ltd., Ongar, United Kingdom Bayer CropScience, Report No.: VC/13/008A, Edition Number: M-464901-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	N	-	Bayer Crop- Science
KCA 7.2.2.3 /03	Hardy, I. A. J.	2013	Isoxaflutole: Kinetic modelling evaluation of water sediment degradation study data to derive water phase DT50 values Battelle UK Ltd., Ongar, United Kingdom Bayer CropScience, Report No.: VC/13/008B, Edition Number: M-464903-01-1 Date: 2013-07-17 GLP/GEP: no, unpublished	N	N	-	Bayer Crop- Science
KCA 7.2.2.4 /01	Ayliffe, J. M.; New- by, S. E.	1995	RPA 201772: Degradation and retention in two water / sediment systems Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000377, Edition Number: M-158508-01-1 Date: 1995-05-04 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.2.2.4 /02	Lowden, P.; Cooper, I.; Simmonds, M.; Burr, C. M.	1996	[14C]-RPA 202248: Adsorption/desorption to and from four soils and an aquatic sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: 11486, Edition Number: M-066483-01-1 Date: 1996-07-17 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.2.2.4 /03	Burr, C. M.	1996	[14C]-RPA203328: Adsorption / desorption to and from four soils and a sediment Rhone-Poulenc Agriculture Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: R000447, Report includes Trial Nos.: 11487 Edition Number: M-158651-01-1 Date: 1996-07-30 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.3.1 /01	Maestracci, M. P	1996	Isoxaflutole - Estimation of the rate of photochemical transformation in the atmosphere under tropospheric conditions Rhone-Poulenc Agro, Lyon, France Bayer CropScience, Report No.: C022447, Report includes Trial Nos.: 95-116 Edition Number: M-213115-01-1 Date: 1996-01-08 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 7.3.1 /02	Kubiak R.	1997	Investigation of the volatilization of 14C-isoxaflutole formulated corresponding to EXP31130A from plant and soil surfaces under laboratory conditions SLFA Neustadt, Neustadt, Germany Bayer CropScience, Report No.: R014793, Report includes Trial Nos.: 97-18 97-19 Edition Number: M-	N	N	-	Bayer Crop- Science

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			189768-01-1 Date: 1997-02-26 GLP/GEP: yes, unpublished				
KCA 7.3.1 /03	Buntain, I. G.	2003	Isoxaflutole: Estimation of degradation by photo-oxidation in air Model calculation according to Atkinson Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C038406, Report includes Trial Nos.: CX/03/081 Edition Number: M-224922-01-1 Date: 2003-12-03 GLP/GEP: no, unpublished	N	N	-	Bayer Crop-Science
KCA 7.3.1 /04	Buntain, I. G.	2003	RPA202248: Estimation of degradation by photo-oxidation in air Model calculation according to Atkinson Battelle AgriFood Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: C038405, Report includes Trial Nos.: CX/03/080 Edition Number: M-224920-01-1 Date: 2003-12-03 GLP/GEP: no, unpublished	N	N	-	Bayer Crop-Science
KCA 7.4.1 /01	Hampton, R. E.; Cappy, J. J.	1995	Rationale for site of 14C-labelling of isoxaflutole (RPA201772) Supporting data Rhone-Poulenc Ag Company, RTP, NC, USA Bayer CropScience, Report No.: R004910, Edition Number: M-166773-01-1 GLP/GEP: no, unpublished	N	N	-	Bayer Crop-Science
KCA 8.1.1.1 /01	N/N	1994	RPA201772 technical - 14-day acute oral LD50 study in bobwhite quail Report No.: R004940, Edition Number: M-166860-01-1 Date: 1994-03-15 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop-Science
KCA 8.1.1.1 /02	N/N	1994	RPA201772 technical: 14-day acute oral LD50 study in mallard ducks , Report No.: R004941, Edition Number: M-166863-01-1 Date: 1994-03-15 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop-Science
KCA 8.1.1.2 /01	N/N	1994	RPA201772 technical - acute dietary LC50 study in bobwhite quail , Report No.: R004938, Edition Number: M-166855-01-1 Date: 1994-05-25 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop-Science
KCA 8.1.1.2 /02	N/N	1994	RPA201772 technical - 8-day acute dietary LC50 study in mallard ducklings , Report No.: R004939, Edition Number: M-166858-01-1 Date: 1994-05-25 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop-Science
KCA 8.1.1.2 /03	N/N	1995	Subacute dietary toxicity (LC50) to the bobwhite quail RPA 202248 Report No.: C022448, Report includes Trial Nos.: RNP479 Edition Number: M-213116-01-1 Date: 1995-12-08 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop-Science
KCA	N/N	1998	RPA 203328: A Dietary LC50 Study with the Northern Bobwhite , Report	Y	N	-	Bayer

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8.1.1.2 /04			No.: B004404, Edition Number: M-241327-01-1 EPA MRID No.: 44693501 Date: 1998-10-15 GLP/GEP: yes, unpublished				Crop- Science
KCA 8.1.1.3 /01	N/N	1999	The Reproductive Toxicity Test of RPA 202248 with the Northern Bob- white (Colinus virginianicus): RPA 202248 Report No.: B002788, Report in- cludes Trial Nos.: 029809 14518 Edition Number: M-238510-01-1 Date: 1999-12-15 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCA 8.1.1.3 /02	N/N	2005	Long-term avian risk assessment of MERLIN - response to the Italian minis- try of health , Report No.: M-254543-01-1, Edition Number: M-254543-01-1 GLP/GEP: n.a., unpublished	Y	N	-	Bayer Crop- Science
KCA 8.2.1 /01	N/N	1993 a	Acute toxicity to bluegill sunfish (Lepomis macrochirus) under flow-through conditions RPA210772 Report No.: R004943, Report includes Trial Nos.: 10566.0493.6283.105 Edition Number: M-166868-01-1 EPA MRID No.: 435732-35 Date: 1993-11-15 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCA 8.2.1 /02	Bettencourt, M. J.	1993 b	RPA201772 - Acute toxicity to rainbow trout (Oncorhynchus mykiss) under flow through conditions Report includes Trial Nos.: 10566.0493.6284.108 Edition Number: M-166876-01-1 EPA MRID No.: 435732-36 Date: 1993- 12-08 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCA 8.2.1 /03	N/N	1995 a	RPA202248 - Acute toxicity (96 hours) to rainbow trout (Oncorhynchus mykiss) under semi-static conditions Report No.: R005355, Edition Number: M-170804-01-1 EPA MRID No.: 439048-22 Date: 1995-11-03 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCA 8.2.1 /04	N/N	1995	RPA203328 - Acute toxicity to rainbow trout (Oncorhynchus mykiss) under flow through conditions , Report No.: R005254, Report includes Trial Nos.: 10566.0194.6328.108 Edition Number: M-170722-01-1 EPA MRID No.: 43904825 Date: 1995-06-22 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCA 8.2.1 /05	N/N	1995	RPA 205834 - Acute toxicity (96 hours) to rainbow trout (Oncorhynchus mykiss) under semi-static conditions , Report No.: C022449, Edition Num- ber: M-213119-01-1 Date: 1995-11-10 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop- Science
KCA 8.2.1 /06	N/N	1994	RPA201772 technical - Acute toxicity to sheepshead minnow (Cyprinodon variegatus) under flow-through conditions Report No.: R002592, Report in- cludes Trial Nos.: 10566.0194.6320.505 Edition Number: M-162973-01-1	Y	N	-	Bayer Crop- Science

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			Date: 1994-07-01 GLP/GEP: yes, unpublished				
KCA 8.2.1 /07	N/N	2000	RPA 202248 - Acute Toxicity to the Sheepshead Minnow (Cyprinodon variegatus) under Static Conditions Report No.: B002804, Report includes Trial Nos.: 10566.6574 G00d #18308 Edition Number: M-238523-01-1 Date: 2000-02-22 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop-Science
KCA 8.2.2 /01	N/N	1995	Isoxaflutole: Fish, juvenile growth test - 28 days , Report No.: C022450, Edition Number: M-213121-01-1 Date: 1995-11-23 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop-Science
KCA 8.2.2 /02	N/N	2013	Early-life stage toxicity of isoxaflutole (tech.) to fish (Pimephales promelas) under flow-through conditions Report No.: EBISX074, Edition Number: M-469327-01-1 Date: 2013-11-13 GLP/GEP: yes, unpublished	Y	N	-	Bayer Crop-Science
KCA 8.2.4.1 /01	Putt, A. E.	1993	RPA201772 - Acute toxicity to daphnids (Daphnia magna) under flow-through conditions Springborn Laboratories, Inc., Environmental Sciences Division, USA Bayer CropScience, Report No.: R004944, Report includes Trial Nos.: 10566.0493.6285.115 Edition Number: M-166871-01-1 Date: 1993-10-06 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop-Science
KCA 8.2.4.1 /02	McElligott, A.; McCahon, P.	1995	RPA202248 - Acute toxicity (48 hours) to daphnids (Daphnia magna) under semi static conditions Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: SA95142, Edition Number: M-170841-03-1 Date: 1995-12-19 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop-Science
KCA 8.2.4.1 /03	Putt, A. E.	1994	RPA203328 - Acute toxicity to daphnids (Daphnia magna) under flow-through conditions Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA Bayer CropScience, Report No.: R005204, Report includes Trial Nos.: 10566.0194.6329.115 Edition Number: M-170649-01-1 EPA MRID No.: 43573241 Date: 1994-09-16 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop-Science
KCA 8.2.4.1 /04	Suteau, P.	1995	RPA205834 - Acute toxicity (48 hours) to daphnids (Daphnia magna) under semi static conditions Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: R005379, Edition Number: M-170847-01-1 Date: 1995-12-13 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop-Science
KCA	McCahon, P.;	1995	RPA205834: Acute toxicity (48 hours) to daphnids (Daphnia magna) under	N	N	-	Bayer

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	Justifica- tion if data protection is claimed	Owner
8.2.4.1 /05	Suteau, P.		semi static conditions Rhone-Poulenc Agro, Sophia Antipolis, France Re- port No.: R005380, Edition Number: M-170850-01-1 GLP/GEP: no, un- published				Crop- Science
KCA 8.2.4.2 /01	Silke, G.	2013	Acute toxicity of isoxaflutole (tech.) to larvae of Chironomus riparius in a 48 h static laboratory test system - LIMIT - test Bayer CropScience, Report No.: EBISN014, Edition Number: M-468785-01-1 Date: 2013-11-05 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.4.2 /02	Bettencourt, M. J.	1994	RPA201772 technical - Acute toxicity to mysid shrimp (Mysidopsis bahia) under flow through conditions Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience, Report No.: R002591, Report includes Trial Nos.: 10566.0194.6319.515 10566.1094.6319.515 Edition Number: M-227961-02- 1 Date: 1994-07-22 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.4.2 /03	Collins, M. K.	1995	RPA202248 - Acute toxicity to mysids (Mysidopsis bahia) under static re- newal conditions Springborn Laboratories, Inc. (SLS), Environmental Sci- ences Division, Wareham, MA, USA Bayer CropScience, Report No.: R005386, Report includes Trial Nos.: 10566.0895.6369.510 Edition Number: M-170861-01-1 EPA MRID No.: 439048-24 Date: 1995-12-22 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.4.2 /04	Sousa, J. V.	1998	RPA 203328 - Acute toxicity to mysids (Mysidopsis bahia) under static acute conditions Springborn Laboratories, Inc., Wareham, MA, USA Report No.: C026471, Report includes Trial Nos.: 10566.0797.6436.510 Edition Number: M-211469-01-1 EPA MRID No.: 44718801 Date: 1998-12-10 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.5.1 /01	McElligott, A	1995	Isoxaflutole - Daphnia magna life cycle (21 day flow-through) chronic toxici- ty study Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: C022451, Edition Number: M-213123-01-1 Date: 1995-11-30 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.5.1 /02	Putt, A. E.	1998	IFT Technical RPA201772 - The chronic toxicity to Daphnia magna under static renewal conditions Springborn Laboratories, Inc. (SLS), Wareham, MA, USA Bayer CropScience, Report No.: 98-10-7505, Report includes Trial Nos.: 10566,0898.6516.130 Edition Number: M-210464-01-2 EPA MRID	N	N	-	Bayer Crop- Science

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			No.: 48660702 Date: 1998-11-10 GLP/GEP: yes, unpublished				
KCA 8.2.5.1 /03	Sousa, J. V.	1995	Isoxaflutole - Chronic toxicity to mysids (Mysidopsis bahia) under flow-through conditions Springborn Laboratories, Inc., Environmental Sciences Division, USA Bayer CropScience, Report No.: R004949, Report includes Trial Nos.: 10566.1294.6352.530 Edition Number: M-166884-01-1 EPA MRID No.: 439048-21 Date: 1995-12-01 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.5.3 /01	Odin-Feurtet, M.	1997	Isoxaflutole - Toxicity to the sediment dwelling chironomid larvae (Chironomus riparius) - 28 days Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: C026473, Edition Number: M-211474-01-1 Date: 1997-12-18 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.5.4 /01	Odin-Feurtet, M.	1997	Isoxaflutole - Toxicity to the sediment dwelling chironomid larvae (Chironomus riparius) - 28 days Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: C026473, Edition Number: M-211474-01-1 Date: 1997-12-18 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.6.1 /01	Hoberg, J. R.	1993	RPA201772 - Toxicity to the the freshwater green alga, Selenastrum capricornutum Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA Bayer CropScience, Report No.: R004955, Report includes Trial Nos.: 10566.0493.6286.430 Edition Number: M-166898-01-1 Date: 1993-09-10 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.6.1 /02	Sewell, J. G.; Bartlett, A. J.	1995	RPA 202248: Algal inhibition test Safepharm Lab. Ltd., Derby, United Kingdom Bayer CropScience, Report No.: C022452, Edition Number: M-213125-01-1 Date: 1995-10-23 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.6.1 /03	Hoberg, J. R.	1995	5-day toxicity to the freshwater green alga, Selenastrum capricornutum RPA203328 Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA BCS, Report No.: R005374, Report includes Trial Nos.: 10566.0595.6367.430 Edition Number: M-170835-01-1 EPA MRID No.: 43904826 Date: 1995-11-22 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.6.1 /04	Sewell, J. G.; Bartlett, A. J.	1995	RPA 205834: Algal inhibition test Safepharm Lab. Ltd., Derby, United Kingdom Bayer CropScience, Report No.: C022453, Edition Number: M-213127-01-1 Date: 1995-10-23 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA	Hoberg, J. R.	1997	RPA202248 technical - Toxicity to the freshwater green alga, (Selenastrum	N	N	-	Bayer

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8.2.6.1 /05			capricornutum) Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA BCS, Report No.: R004952, Report includes Trial Nos.: 10566.0797.6435.430 Edition Number: M-166891-01-1 EPA MRID No.: 44399908 Date: 1997-09-17 GLP/GEP: yes, unpublished				Crop- Science
KCA 8.2.6.2 /01	Hoberg, J. R.	1994	RPA201772 technical - Acute toxicity to the marine diatom, Skeletonema costatum Springborn Laboratories, Inc., Environmental Sciences Division, USA Bayer CropScience, Report No.: R002577, Report includes Trial Nos.: 10566.0194.6322.450 Edition Number: M-162947-01-1 Date: 1994-07-01 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.6.2 /02	Hoberg, J. R.	1994	RPA201772 technical - Acute toxicity to the freshwater blue-green alga, Anabaena flos-aquae Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA Report No.: R004947, Report includes Trial Nos.: 10566.0194.6324.420 Edition Number: M-166879-01-1 Date: 1994-06-10 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.6.2 /03	Hoberg, J. R.	1994	RPA201772 technical - Acute toxicity to the freshwater diatom, Navicula pelliculosa Springborn Laboratories, Inc. (SLS), Environmental Sciences Division, Wareham, MA, USA Bayer CropScience, Report No.: R004948, Report includes Trial Nos.: 10566.0194.6323.440 Edition Number: M-166881-01-1 Date: 1994-06-10 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.6.2 /04	Hager, J.	2013	Isoxaflutole technical: Recalculation of 72h endpoint for Skeletonema costatum (Original study report no. 94-6-5302) Bayer CropScience, Report No.: M-468837-01-1, Edition Number: M-468837-01-1 GLP/GEP: n.a., unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.7 /01	Hoberg, J. R.	1994	RPA201772 technical - Toxicity to duckweed, Lemna gibba Springborn Laboratories, Inc., Environmental Sciences Division, USA Bayer CropScience, Report No.: R004954, Report includes Trial Nos.: 10566.0194.6325.410 Edition Number: M-166896-01-1 Date: 1994-07-01 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.2.7 /02	Hoberg, J. R.	1999	Isoxaflutole (IFT) - Toxicity to the duckweed, Lemna gibba - Code: AE B197278 Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience, Report No.: C024183, Report includes Trial Nos.: 10566.1198.6532.410 Edition Number: M-216432-01-1 Date: 1999-03-19	N	N	-	Bayer Crop- Science

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			GLP/GEP: yes, unpublished				
KCA 8.2.7 /03	Hoberg, J. R.	1997	RPA 202248 technical - Toxicity to duckweed, Lemna gibba Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience, Report No.: R004951, Report includes Trial Nos.: 10566.0797.6434.410 Edition Number: M-166889-01-1 EPA MRID No.: 44399909 Date: 1997-09-16 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop-Science
KCA 8.2.7 /04	Bruns, E.; Solga, A.	2013	Isoxaflutole technical: Recalculation of 9- days endpoints for Lemna gibba (Original Study Report No. 94-6-5319) Bayer CropScience, Report No.: M-449195-01-1, Edition Number: M-449195-01-1 GLP/GEP: n.a., unpublished	N	N	-	Bayer Crop-Science
KCA 8.2.7 /05	Banman, C.S., Moore, S.	2013	Toxicity of isoxaflutole technical to the aquatic macrophyte, Myriophyllum spicatum SynTech Research Laboratory, Stilwell, Kansas, USA Bayer Crop-Science, Report No.: EBISX046, Edition Number: M-452561-01-1 Date: 2013-04-22 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop-Science
KCA 8.2.7 /06	Hoberg, J. R.	1997	RPA203328 technical - Toxicity to the duckweed, Lemna gibba Springborn Laboratories, Inc., Wareham, MA, USA Bayer CropScience, Report No.: R004953, Report includes Trial Nos.: 10566.0797.6441.410 Edition Number: M-166893-01-1 EPA MRID No.: 44399910 Date: 1997-09-17 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop-Science
KCA 8.2.7 /07	Hoberg, J. R.	2004	RPA 205834 - Toxicity To Duckweed, Lemna gibba Springborn Smithers Laboratories Bayer CropScience, Report No.: B004561, Report includes Trial Nos.: 13798.6107 Edition Number: M-241470-01-1 Date: 2004-01-08 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop-Science
KCA 8.2.8 /01	Banman, C. S.; Alexander, T. M.; Lam, C. V.	2011	Acute toxicity of isoxaflutole to Xenopus laevis under flow-through conditions Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: EBISY004, Edition Number: M-410610-01-1 EPA MRID No.: 48660711 Date: 2011-07-11 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop-Science
KCA 8.3.1.1.1 /01	Petto, R.	1994	Laboratory testing for toxicity (acute contact and oral LD50) of RPA201772 to honey bees (Apis mellifera L.) (Hymenoptera, Apidae) RCC Umwelt-chemie GmbH & Co. KG, Rossdorf, Germany Bayer CropScience, Report No.: M-170652-02-1, Edition Number: M-170652-02-1 Date: 1994-09-26 ...Amended: 1996-02-14 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop-Science

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KCA 8.3.1.1.2 /02	Schmitzer, S.	2012	Effects of isoxaflutole tech. (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 72931035, Edition Number: M-441348-01-1 Date: 2012-11-08 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.4 /01	Handley, J. W.; Wet- ton, P. M.	1993	The acute toxicity of RPA201772 to earthworms (<i>Eisenia foetida</i>) SafePharm Lab. Ltd., Derby, United Kingdom Bayer CropScience, Report No.: R002139, Edition Number: M-162062-01-1 Date: 1993-07-21 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KPA 8.4 /02	Odin-Feurtet, M.	1997	RPA 203328 - Acute toxicity (14-day) to earthworms (<i>Eisenia foetida</i>) - Arti- ficial soil method Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: C026475, Edition Number: M-211477-01-1 Date: 1997-10-28 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.4.1 /01	Kratz M. A.	2013	Isoxaflutole (AE B197278) technical: Effects on survival, growth and repro- duction on the earthworm <i>Eisenia fetida</i> tested in artificial soil Bayer Crop- Science, Report No.: kra-Rg-R-129/12, Edition Number: M-450435-01-1 Date: 2013-03-25 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.4.1 /02	Kratz M. A.	2012	Isoxaflutole-RPA202248: Effects on survival, growth and reproduction on the earthworm <i>Eisenia fetida</i> tested in artificial soil Bayer CropScience, Report No.: KRA-RG-R-132/12, Edition Number: M-442776-01-1 Date: 2012-11-29 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.4.1 /03	Moser, T.; Scheff- czyk, A.	2004	Isoxaflutole-RPA203328 (AE B197555): Reproduction toxicity to earthworm <i>Eisenia fetida</i> in artificial soil ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience, Report No.: C041342, Edition Number: M- 230530-01-1 Date: 2004-04-26 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.4.2.1 /01	Frommholz, U.	2011	Isoxaflutole a.s.: Influence on the reproduction of the collembolan species <i>Folsomia candida</i> tested in artificial soil Bayer CropScience, Report No.: FRM-COLL-124/11, Edition Number: M-416012-01-1 Date: 2011-10-14 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.4.2.1 /02	Kratz M. A.	2011	Isoxaflutole a. s.: Influence on mortality and reproduction on the soil mite species <i>Hypoaspis aculeifer</i> tested in artificial soil Bayer CropScience, Report No.: KRA-HR-46/11, Edition Number: M-416751-01-1 Date: 2011-11-08	N	N	-	Bayer Crop- Science

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			GLP/GEP: yes, unpublished				
KCA 8.4.2.1 /03	Frommholz, U.	2011	Isoxaflutole-RPA202248 (AE 0540092): Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Bayer Crop-Science, Report No.: FRM-COLL-134/11, Edition Number: M-420112-01-1 Date: 2011-12-16 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.4.2.1 /04	Kratz M. A.	2011	Isoxaflutole-RPA202248 (AE 0540092): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil Bayer CropScience, Report No.: KRA-HR-63/11, Edition Number: M-417912-01-1 Date: 2011-11-25 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.4.2.1 /05	Frommholz, U.	2011	Isoxaflutole-RPA203328 (AE B197555): Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Bayer Crop-Science, Report No.: FRM-COLL-135/11, Edition Number: M-420062-01-1 Date: 2011-12-15 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.4.2.1 /06	Kratz M. A.	2011	Isoxaflutole-RPA203328 (AE B197555): Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil Bayer CropScience, Report No.: KRA-HR-64/11, Edition Number: M-419849-01-1 Date: 2011-12-14 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.5 /01	Forster, J.	1994	A laboratory assessment of the effects of RPA 201772 on soil microflora respiration and nitrogen turnover according to BBA guidelines VI 1-1 (1990) Euro Laboratories Ltd., Bedfordshire, United Kingdom Bayer CropScience, Report No.: C022454, Edition Number: M-213129-01-1 Date: 1994-12-02 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.5 /02	McMurray, A.	1997	A laboratory assessment of the effects of RPA 203328 on soil microflora respiration and nitrogen transformations according to EPPO Bulletin 24, 1-16 (1994) Chemex International plc, United Kingdom Bayer CropScience, Report No.: C038791, Edition Number: M-225762-01-1 Date: 1997-12-18 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.5 /03	McCahon, P.	1997	Response to requirement for additional ecotoxicology data Subject: Isoxaflutole monograph Response document to the monograph Appendix 3 Rhone-Poulenc Agro, Sophia Antipolis, France Bayer CropScience, Report No.: C038804, Edition Number: M-225777-01-1 GLP/GEP: no, unpublished	N	N	-	Bayer Crop- Science

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KCA 8.5 /04	Schulz, L.	2013	Isoxaflutole-RPA202248 (BCS-AB59005): Effects on the activity of soil microflora (nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 084 N, Edition Number: M-469915-01-1 Date: 2013-11-19 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- Science
KCA 8.8 /01	Hertl, J.	2001	Toxicity of Isoxaflutole, substance technical; Code AE B197278 00 1D99 0001 to Activated Sludge in a Respiration Test IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: B003605, Edition Number: M-240627-01-1 Date: 2001-09-24 GLP/GEP: yes, unpublished	N	N	-	Bayer Crop- 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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