

REGISTRATION REPORT

Part A

Risk Management

Product code: A23109A

Product name: ORONDIS VIP

Chemical active substances:

Metalaxyl-M, 174.4 g/L

Oxathiapiprolin, 30 g/L

Central Zone/Interzonal

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

Poland

(New authorisation)

Applicant: Syngenta

Submission date: June 2022, updated:

July 2022, August 2022, March 2023, July 2023, October 2023

MS Finalisation date: December 2022/July 2023

(initial National Assessment)

December 2023, updated April 2024 (final National Assessment)

updated July 2024

Version history

When	What
June 2022	Version 1 Applicant
July 2022	Version 2 Applicant Country data and Intended Uses corrected, new studies highlighted.
August 2022	Version 3 Applicant Appendix 4: Yellow highlights for previously included Syngenta studies are removed. New references are added for Corteva studies. Errors in reference list for Corteva studies are corrected. All changes are highlighted in green.
December 2022	zRMS finalized dRR evaluation (in the scope of ecotoxicology, fate and behaviour)
March 2023	GAP table update for PL (<i>Bremia lactucae</i> on lettuce is considered under Art. 33, not 51)
July 2023	Appendix 4: additional residues references included providing further open leaf lettuce residue trials data (field and protected)
July 2023	Initial zRMS assessment (other section) In order to facilitate tracking of changes of the intended uses of the product due to the performed evaluation, amendments of the GAP table and in the product label (Appendix 2) and Lists of data considered for national authorization (Appendix 4) are highlighted in grey , while not agreed use pattern is struck through and shaded . Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
October 2023	Updates to <ul style="list-style-type: none"> 2.51, PPE requirements for protected crops Amendment of non-dietary risk assessment to include assessment with EFSA 2022 OPEX model Update of PEC_{GW} values Review of Appendix 4
December 2023	Final report (National Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow . Not agreed or not relevant information are struck through and shaded for transparency.
April 2024	This RR version contains adjusted label informations regarding RMM based on accepted NDE assessment (refer to the RR B6). Changes in the label has been highlighted in yellow shading. Not agreed or not relevant information are struck through and shaded for transparency.
July 2024	Final report - updated with regard to the provisions of COMMISSION IMPLEMENTING REGULATION (EU) 2024/1718 of 19 June 2024 amending Implementing Regulations (EU) 2020/617 and (EU) No 540/2011 as regards the conditions of approval of the active substance metalaxyl-M. Additional information/assessments included by the zRMS in the report are highlighted in green . Not agreed or not relevant information are struck through and shaded for transparency.

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Syngenta. Poland was the central and interzonal RMS for the evaluation.

The application was for approval of ‘Orondis’ VIP (A23109A), a dispersible concentrate (DC) containing 174.4 g/L metalaxyl-M and 30 g/L oxathiapiprolin, for use as a fungicide on field and protected vegetable crops.

To obtain authorization the product A23109A, must (where appropriate) meet the conditions of a.s. EU inclusion and be supported by a dossier satisfying the requirements of Commission Regulation (EU) No. 284/2013, and the associated Annex, which repeals Commission Regulation (EU) No 545/2011 which, under Regulation (EC) 1107/2009, replaced the requirements of Annex III to Directive 91/414/EEC.

The application was submitted in order to allow the authorization of this product/use in the concerned Member State Poland in accordance with the above.

1.2 Letters of Access

Where Syngenta relies on data belonging to a third party that are included in the dossier, then the ownership of the data is indicated in **Appendix 4** of this document and also in the corresponding reference lists in **Appendix 1** of the **Registration Report, Part B Sections 1-10** and a letter of access to that data or reference to such is provided in Appendix 3 of this document.

1.3 Justification for submission of tests and studies

Art. 33 (3) c Justification of steps taken to avoid animal testing and duplication of such testing:

This is a new plant protection product, which is intended to be authorized in Member States for the first time. There is no duplication of vertebrate studies and extrapolation to data of similar formulations is not possible. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.

Art. 33 (3) d Reasons for submission of tests and study reports:

This a new plant protection product and there is no EU derogation allowing for these data points to be addressed by extrapolation from existing data; therefore in order to obtain approval new tests were required and the study reports are provided.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of A23109A, in accordance with Article 59 of Regulation (EC) No. 1107/2009, it is indicated in **Appendix 4** of this document.

2 Details of the authorization decision

2.1 Product identity

Product code	A23109A
Product name in MS	Orondis VIP
Authorization number	New registration
Function	Fungicide
Applicant	Syngenta Polska Sp. z.o.o.
Active substance(s) (incl. content)	174.4 g/L metalaxyl-M and 30 g/L oxathiapiprolin
Formulation type	Dispersible Concentrate (DC)
Packaging	1L and 5L HDPE canisters - professional user
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identity	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

The authorization can be granted.

~~The current specification of the metalaxyl M source is not acceptable. The authorisation of the product should be only possible after the revision of the regulation Reg. (EU) 2020/617 and full acceptance of the proposed source of production of the active substance metalaxyl M.~~

2.3 Substances of concern for national monitoring

Not applicable.



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 sensitisation, Sub-category 1B: H317: May cause an allergic skin reaction. Eye irritation, Sub-category 2: H319 Long-term (chronic) aquatic hazard, Category 2: H411: Toxic to aquatic life with long lasting effects
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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:	  GHS07 GHS09
Signal word:	Warning
Hazard statement(s):	H317 May cause an allergic skin reaction H319 Causes serious eye irritation ¹

	H411 Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	Prevention: P261 Avoid breathing mist or vapours P280 Wear protective gloves Response: P264 Wash thoroughly after handling P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical advice/ attention. P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention P362 + P364 Take off contaminated clothing and wash it before reuse P391 Collect spillage Disposal: P501 Dispose of contents/ container to an approved waste disposal plant
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

¹ Differences in hazard statements may arise between the B.6 and the SDS, due to the difference in Regulation (EC) No 1272/2008 and the GHS for classification.

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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

	Refer to national product label
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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:	
	<u>PPE requirements: Outdoor</u> Handheld manual and knapsack spray applications: gloves during mixing and loading, and during application <u>PPE requirements: Protected crops</u> Application during the intensive crop scenario, impermeable coveralls. Additional PPE is required due to the classification of the product with protective gloves/protective clothing (impermeable coveralls)/eye protection during mix-ing/loading/application.
Worker protection:	
None	Not required
Integrated pest management (IPM)/sustainable use:	
None	n/a
Environmental protection	

None	n/a
Other specific restrictions	
None	n/a

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

Integrated pest management (IPM)/sustainable use:	
None	n/a

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.
None	n/a	n/a
Environmental protection:		Relevant for use no.
None	n/a	n/a

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 2, date: 2023-12-07

PPP (product name/code): Orondis VIP / A23109A
Active substance 1: Metalaxyl-M
Active substance 2: Oxathiapiprolin
Applicant: Syngenta
Zone(s): central/interzonal ^(d)
Verified by MS: yes
Field of use: Fungicide

Formulation type: DC
Conc. of as 1: 174.4 g/L ^(c)
Conc. of as 2: 30 g/L ^(c)
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15*							
Use- No. ^(e)	Membe r 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: developmental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remark s: e.g. g safener/ synergist per ha ^(f)	zRMS Conclusion							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop / season	Min. interval between applicati ons (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g MFX/ha a) max. rate per appl. b) max. total rate per crop/season	g OXTp/ha a) max. rate per appl. b) max. total rate per crop /season	Water L/ha min/max			Phys-chem	Analytical methods	Toxicology	Residues	Groundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																						
PL-1	Poland	Baby leaves	F	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-3	Poland	Broccoli [BRSOK]	F	<i>Hyaloperonospor a parasitica</i> [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20-21	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-3a	Poland	Broccoli [BRSOK]	F	<i>Albugo sp.</i> [ALBUSP]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20-21	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-5	Poland	Brussels sprouts [BRSEF]	F	<i>Hyaloperonospor a parasitica</i> [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20-21	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.

PL-5a	Poland	Brussels sprouts [BRSOB]	F	<i>Albugo</i> sp. [ALBUSP]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-7	Poland	Cauliflower [BRSOB]	F	<i>Hyaloperonospora parasitica</i> [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-7a	Poland	Cauliflower [BRSOB]	F	<i>Albugo</i> sp. [ALBUSP]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-8	Poland	Chards and beet leaves [BEAVD]	F	<i>Peronospora farinosa</i> f. sp. <i>spinaciae</i> [PEROFS]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-600	10	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-9	Poland	Chicory [CICIN]	F	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-10	Poland	Chives [ALLSC]	F	<i>Phytophthora porri</i> [PHYTPO]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	N	R	A	A	n.r.
PL-11	Poland	Common purslane [POROL]	F	<i>Peronospora farinosa</i> f. sp. <i>spinaciae</i> [PEROFS]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-600	10	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-12	Poland	Cress [CRESS]	F	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-14	Poland	Curly kale [BRSOC]	F	<i>Hyaloperonospora parasitica</i> [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	N	R	A	A	n.r.

PL-14a	Poland	Curly kale [BRSOC]	F	<i>Albugo</i> sp. [ALBUSP]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	N	R	A	A	n.r.
PL-15	Poland	Endive [CICEN]	F	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-16	Poland	Escarole [CICEL]	F	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-17	Poland	Garlic [ALLSA]	F	<i>Phytophthora porri</i> [PHYTPO]	Foliar	BBCH 12 - 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-18	Poland	Garlic [ALLSA]	F	<i>Peronospora destructor</i> [PERODE]	Foliar	BBCH 12 - 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-20	Poland	Head cabbage [BRSOL]	F	<i>Hyaloperonospora parasitica</i> [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21		A	A	A	A	R	A	A	N
PL-20a	Poland	Head cabbage [BRSOL]	F	<i>Albugo</i> sp. [ALBUSP]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-21	Poland	Herbs and edible flowers [NNNEF]	F	<i>Phytophthora/Do wny mildew</i> [SCLPST]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	N except basil and edible flowers (0256 080)	R	A	A	n.r.
PL-23	Poland	Kale [BRSOA]	F	<i>Hyaloperonospora parasitica</i> [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	N	R	A	A	n.r.
PL-23a	Poland	Kale [BRSOA]	F	<i>Albugo</i> sp. [ALBUSP]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	N	R	A	A	n.r.

PL-24	Poland	Lamb's lettuce [VLLLO]	F	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-26	Poland	Leafy brassica [3LFBC]	F	<i>Hyaloperonospora parasitica</i> [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20-21	Minor Use – Art 51	A	A	A	N	R	A	A	n.r.
PL-26a	Poland	Leafy brassica [3LFBC]	F	<i>Albugo</i> sp. [ALBUSP]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20-21	Minor Use – Art 51	A	A	A	N	R	A	A	n.r.
PL-27	Poland	Leek [ALLPO]	F	<i>Peronospora destructor</i> [PERODE]	Foliar	BBCH 12 - 48	a) 2 b) 2	12-14	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-28	Poland	Leek [ALLPO]	F	<i>Phytophthora porri</i> [PHYTPO]	Foliar	BBCH 12 - 48	a) 2 b) 2	12-14	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14		A	A	A	A	R	A	A	N
PL-29	Poland	Lettuce [LACSA]	F	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	A
PL-30	Poland	Mustard, red	F	<i>Hyaloperonospora parasitica</i> [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20-21	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-31	Poland	Onion [ALLCE]	F	<i>Phytophthora porri</i> [PHYTPO]	Foliar	BBCH 12 - 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-32	Poland	Onion [ALLCE]	F	<i>Peronospora destructor</i> [PERODE]	Foliar	BBCH 12 - 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14		A	A	A	A	R	A	A	A
PL-33	Poland	Parsley [PARCR]	F	<i>Downy Mildew - Plasmopara umbelliferarum</i> [PLASCR]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	N	R	A	A	n.r.

PL-37	Poland	Pe-tsai [BRSPK]	F	<i>Hyaloperonospora parasitica</i> [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	N	R	A	A	n.r.
PL-37a	Poland	Pe-tsai [BRSPK]	F	<i>Albugo</i> sp. [ALBUSP]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	N	R	A	A	n.r.
PL-38	Poland	Purple-vein rocket [ERUVE]	F	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-40	Poland	Savoy cabbage [BRSOS]	F	<i>Hyaloperonospora parasitica</i> [PEROPA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-40a	Poland	Savoy cabbage [BRSOS]	F	<i>Albugo</i> sp. [ALBUSP]	Foliar	BBCH 12 - 49	a) 2 b) 2	7-10	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	20 21	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-41	Poland	Shallot [ALLAS]	F	<i>Phytophthora porri</i> [PHYTPO]	Foliar	BBCH 12 - 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-42	Poland	Shallot [ALLAS]	F	<i>Peronospora destructor</i> [PERODE]	Foliar	BBCH 12 - 48	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-43	Poland	Spinach [SPQOL]	F	<i>Peronospora farinosa</i> f. sp. <i>spinaciae</i> [PEROFS]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-600	10	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-44	Poland	Spring, welsh and green onion [ALLFI]	F	<i>Peronospora destructor</i> [PERODE]	Foliar	BBCH 12 - 48	a) 2 b) 2	12-14	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.
PL-45	Poland	Spring, welsh and green onion [ALLFI]	F	<i>Phytophthora porri</i> [PHYTPO]	Foliar	BBCH 12 - 48	a) 2 b) 2	12-14	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	14	Minor Use – Art 51	A	A	A	A	R	A	A	n.r.

PL-46	Poland	Watercress [NAAOF]	F	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
Minor uses according to Article 51 (zonal uses)																						
None																						
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)																						
PL-47	Poland	Baby leaves	G	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-48	Poland	Chicory [CICIN]	G	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-49	Poland	Cress [CRESS]	G	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-50	Poland	Endive [CICEN]	G	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.

PL-51	Poland	Escarole [CICEL]	G	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-52	Poland	Lamb's lettuce [VLLLO]	G	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-53	Poland	Lettuce [LACSA]	G	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
PL-54	Poland	Purple-vein rocket [ERUVE]	G	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-55	Poland	Watercress [NAAOF]	G	<i>Bremia lactucae</i> [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	N	R	A	A	n.r.

Minor uses according to Article 51 (interzonal uses)

None

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/m ³ 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
15	Overall conclusions - explanation for the column 15 is below *

* Explanation for column 15 “Overall conclusions”

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant

3 Background of authorization decision and risk management

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

Orondis VIP is a dispersible concentrate (DC) formulation. 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 a brownish, clear liquid, with a slightly chemical odour. It is not explosive, has no oxidising properties. The product has no flash point below 200°C. It has an auto-ignition temperature of 400°C ± 12°C. In aqueous solution, it has a pH value around 4.3 at 25°C.

There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C, 14 and 28 days at 54 °C, neither the active ingredient content nor the technical properties changed. The stability data indicate a shelf life of at least 2 3 years at ambient temperature when stored in high density polyethylene (HDPE) packaging.

The formulation has been stored for 2 years at 25°C. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.

The technical characteristics of A23109A are acceptable for a DC formulation.

The product A23109A is not recommended as tank mix with other products.

According to Regulation (EC) No. 1272/2008, no specific labelling or classification is proposed based on the measured physico-chemical properties of A23109A.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

According to Regulation (EC) No. 1272/2008 no specific labelling or classification is proposed based on the measured physico-chemical properties of A23109A.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

According to Regulation (EC) No. 1272/2008 no specific labelling or classification is proposed based on the measured physico-chemical properties of product A23109A.

Compliance with FAO specifications:

There is no FAO specification for A23109A.

Formulation used for tests

All physico-chemical endpoints were measured using A23109A. Thus, no bridging to other formulations is required.

3.2 Efficacy (Part B, Section 3)

A23109A is a dispersible concentrate (DC) containing 30 g oxathiapiprolin and 174.4 g metalaxyl-M (R-enantiomer) per litre product. A23109A is applied as a foliar spray for the control of Oomycete pathogens on leafy vegetable crops, bulb crops and brassica crops

Oxathiapiprolin belongs to the FRAC Group 49. It is a preventive fungicide with limited curative, and residual activity against oomycete fungi and used for the control of *Phytophthora* and downy mildews of numerous crops. Oxathiapiprolin belongs to the chemical group Piperidinyl thiazole isoxazolines, mode of action OSBPI oxysterol binding protein homologue inhibition. Oxathiapiprolin inhibits an oxysterol binding protein (OSBP) homologue. Oxysterol binding proteins are implicated in the movement of lipids between membranes, among other processes. Inhibiting OSBP may disrupt other processes in the fungal cell, such as signaling, maintaining cell membranes, and the formation of more complex lipids that are essential for the cell to survive.

Metalaxyl-M belongs to the phenylamides (PAs) FRAC Group 4 which control Oomycetes (the downy mildews of the *Peronosporales* and *Sclerosporales*, as well as *Pythiales* (e.g., *Phytophthora* and *Pythium* spp.) Metalaxyl-M penetrates the plant tissue rapidly, is translocated acropetally within the plant and

inhibits rRNA biosynthesis (polymerase complex I) in the target pathogens.

3.3 Efficacy data

Preliminary tests

Component justification of the product A23109A is primarily based on resistance management strategy. A23109A is composed of two effective active ingredients against downy mildews, OXTP and MFX. Component justification trials demonstrated the efficacy benefit of the combination of OXTP and MFX, in A23109A and the solo a.i. efficacy at the a.i. rates in the mixture to confirm their efficacy at the mixture rate on main representative pathogens targeted by A23109A.

A23109A contents 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer or 180 g/L MFX global definition R+S enantiomer) and brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 - 90 g/ha MFX (EU - global MFX definition).

Zonal (field) uses

A total of 11 trials on *Bremia lactucae* in lettuce (6x in Maritime and 5x in North-East EPPO zone) are summarized for component justification of A23109A.

A total of 11 trials on *Peronospora destructor* in onion (8x in Maritime and 3x in North-East EPPO zone) are summarized for component justification of A23109A.

A total of 7 trials on *Peronospora* spp. in brassica crops (5x in Maritime and 2x in North-East zone) are summarized for component justification of A23109A.

All the set of trials were carried out over seasons 2019 and 2020.

Interzonal (protected) uses

A total of 6 trials on *Bremia lactucae* in lettuce under protected conditions is presented and summarized for component justification of A23109A.

Please note the rate of MFX in A23109A is based on EU MFX definition is 87.2 g ai/ha (although indicated 90 g ai/ha in the trial reports and tables below, based on global definition (R+S enantiomer). Also, the rate of MFX in A13947A is 88.4 g MFX/ha based on EU definition.

In summary, the combination of OXTP and MFX in the product A23109A will provide effective and robust control in terms of severity against downy mildews on lettuce.

Minimum effective dose tests

A23109A contains 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer) and at its targeted rate of 0.5 L PR/ha, delivers 15 g/ha OXTP + 87.2g/ha MFX.

Zonal (field) uses

A total of 20 field were established to determine the minimum effective dose for the control of the *Bremia lactucae* on lettuce. A23109A was tested in the range 0.25 to 0.5 L PR/ha. Trials were conducted in field conditions in Maritime and North-East EPPO zones.

A total of 17 field trials were established to determine the minimum effective dose for the control of *Peronospora destructor* on onion. A23109A was tested in the range 0.25 to 0.5 L PR/ha. Trials were conducted in Maritime, Mediterranean and North-East EPPO zones.

A total of 9 field trials were established to determine the minimum effective dose for the control of the *Phytophthora porri* on leek. A23109A was tested in the range 0.25 to 0.5 L PR/ha. Trials were conducted

in Maritime EPPO zone.

A total of 11 field trials were established to determine the minimum effective dose for the control of *Peronospora* spp. on brassica crops. A23109A was tested in the range 0.25 to 0.5 L PR/ha. Trials were conducted in Maritime and North-East EPPO zones.

Considering the results and Resistance Management considerations the proposed rate of 0.5 L PR/ha should be considered the minimum effective dose to deliver robust control of symptoms of *Bremia lactucae* on lettuce (field and greenhouse use), *Peronospora destructor* on onion, *Phytophthora porri* on leek and *Peronospora* spp. on brassica crops, providing robust disease control under a wide range of environmental conditions.

Interzonal (protected) uses

A total of 9 protected trials were established to determine the minimum effective dose for the control of the *Bremia lactucae* on lettuce. A23109A was tested in the range 0.25 to 0.5 L PR/ha.

Considering the results and Resistance Management considerations the proposed rate of 0.5 L PR/ha should be considered the minimum effective dose to deliver robust control of symptoms of *Bremia lactucae* on lettuce providing robust disease control under protected conditions.

Efficacy tests

Zonal (field) uses

***Bremia lactucae* on lettuce (Field)**

Efficacy data for *Bremia lactucae* on lettuce are presented from 8 efficacy trials conducted in the EPPO Maritime zone. Assessments were made for pest severity and pest incidence. The standard Revus (A12946B) at 0.6 L PR/ha was used in all trials for comparison with A23109A at 0.5 L PR/ha. Results from Belgium, Germany and France obtained over 2 seasons (2019 and 2020) demonstrated that A23109A at the proposed label rate of 0.5 L PR/ha exceeded the efficacy of a commercial standard. This rate should thus be considered effective against *Bremia lactucae* on lettuce in the Maritime EPPO zone.

Efficacy data for *Bremia lactucae* on lettuce are presented from 6 efficacy trials conducted in the EPPO North- East zone. Assessments were made for pest severity and pest. The standard Revus (A12946B) at 0.6 L PR/ha was used in all trials for comparison with A23109A at 0.5 L PR/ha. Results from Poland obtained over 2 seasons (2019 and 2020) demonstrated that A23109A at the proposed label rate of 0.5 L PR/ha exceeded the efficacy of the commercial standard Revus. This rate should thus be considered effective against *Bremia lactucae* on lettuce in the North-East EPPO zone.

The environmental condition experienced in the EPPO maritime zone (mild and wetter) mean than trials data from this zone could be considered a worst case. Claims for *Bremia lactucae* on lettuce can be extrapolated from the EPPO Maritime data provided for EPPO South-East zone.

A total of 14 open field trials were carried out in support of the Central Zone submission to evaluate the efficacy of A23109A for the control of *Bremia lactucae* in lettuce in seasons 2019 and 2020. In summary the disease level of infection in untreated plots was adequate to validate the trials and reliably assess the efficacy of A23109A.

According to EPPO extrapolation Table 14/19578: “Diseases on leafy vegetables”, efficacy data against *Bremia lactucae* in lettuce can be extrapolated to the targeted crops: baby leaves, chards and beet leaves, chicory, chives, common purslane, cress, endive, escarole, herbs and edible flowers, lamb's lettuce, parsley, purple-vein rocket, watercress, iceberg lettuce under field conditions.

***Peronospora destructor* on onion(field)**

Efficacy data for *Peronospora destructor* on onion are presented from 9 efficacy conducted in the EPPO Maritime zone. Assessments were made for pest severity and pest incidence. The standard Infinito at 1.6

L PR/ha was used in all trials for comparison with A23109A at 0.5 L PR/ha. Results from Belgium, Czech Republic, France and The Netherlands obtained over 2 seasons (2019 and 2020) demonstrated that A23109A at the proposed label rate of 0.5 L PR/ha exceeded the efficacy of the commercial standard Infinito. This rate should thus be considered effective against *Peronospora destructor* on onion in the Maritime EPPO zone.

Efficacy data for *Peronospora destructor* on onion are presented from 4 efficacy trials conducted in the EPPO North-East zone. Assessments were made for pest severity and pest incidence. Results from Poland obtained over 3 seasons (2019, 2020 and 2021) demonstrated that A23109A at the proposed label rate of 0.5 L PR/ha exceeded the efficacy of the commercial standards Infinito and Amistar 250SC. This rate should thus be considered effective against *Peronospora destructor* on onion in the North-East EPPO zone.

The environmental condition experienced in the EPPO maritime zone (mild and wetter) mean than trials data from this zone could be considered a worst case. Claims for *Peronospora destructor* on onion can be extrapolated from the EPPO Maritime data provided for EPPO South-East zone.

A total of 13 open field trials were conducted in support of the Central Zone submission to evaluate the efficacy of A23109A for the control of *Peronospora destructor* on onion in seasons 2019 and 2020. In summary the disease level of infection in untreated plots was adequate to validate the trials and reliably assess the efficacy of A23109A.

According to EPPO extrapolation Table 14/20180: “Diseases on Allium vegetables”, efficacy data against *Peronospora destructor* on onion can be extrapolated to the targeted crops: garlic, shallot, spring, Welsh and green onion under field conditions.

***Phytophthora porri* on leek (field)**

Efficacy data for *Phytophthora porri* in leek are presented from 9 efficacy trials conducted in EPPO Maritime zone. Assessments were made for pest severity and pest incidence. The standard Infinito at 1.6 L PR/ha was used in all trials for comparison with A23109A at 0.5 L PR/ha. Results from Belgium, France and The Netherlands obtained over 2 seasons (2019 and 2020) demonstrated that A23109A at the proposed label rate of 0.5 L PR/ha exceeded in most of the cases the efficacy of the commercial standard. This rate should thus be considered effective against *Phytophthora porri* on leek in the Maritime EPPO zone.

The environmental conditions experienced in the EPPO Maritime zone (mild and wetter) mean than trials data from this zone could be considered a worst case. Claims for *Phytophthora porri* in leek can be extrapolated from the EPPO Maritime data provided for EPPO South-East zone.

According to EPPO extrapolation Table 14/20180: “Diseases on Allium vegetables”, efficacy data against *Phytophthora porri* in leek can be extrapolated to the targeted crops: garlic, shallot, spring, welsh and green onion under field conditions.

***Peronospora* spp. on brassica crops (field)**

Efficacy data for *Peronospora* spp. (*Peronospora brassicae*, *Hyaloperonospora parasitica* and *Peronospora* sp.) on brassica crops are presented from 5 efficacy trials conducted in EPPO Maritime zone. Assessments were conducted for pest severity and pest incidence. The standard Infinito at 1.6 L PR/ha was used in all trials for comparison with A23109A at 0.5 L PR/ha. Results from Belgium, Germany and The Netherlands obtained over 2 seasons (2019 and 2020) demonstrated that A23109A at the proposed label rate of 0.5 L PR/ha exceeded the efficacy of the commercial standard Infinito. This rate should thus be considered effective against *Peronospora* spp. on brassica crops in the Maritime EPPO zone.

Efficacy data for *Peronospora* spp. (*Peronospora brassicae* and *Hyaloperonospora parasitica*) on brassica crops are presented from 6 efficacy trials conducted in EPPO North-East zone. Assessments for

pest severity and pest incidence. The standard Infinito at 1.6 L PR/ha was used in all trials for comparison with A23109A at 0.5 L PR/ha. Results from Poland obtained over 2 seasons (2019 and 2020) demonstrated that A23109A at the proposed label rate of 0.5 L PR/ha exceeded the efficacy of a commercial standard. This rate should thus be considered effective against *Peronospora* spp. on brassica crops in the North-East EPPO zone.

The environmental condition experienced in the EPPO maritime zone (mild and wetter) mean than trials data from this zone could be considered a worst case. Claims for *Peronospora* spp. (*Peronospora brassicae* and *Hyaloperonospora parasitica*) on brassica crops thus can be extrapolated from the maritime data provided to EPPO South-East zone.

A total of 11 open field trials were conducted in support of the Central zone Submission, to evaluate the efficacy of A23109A for the control of *Peronospora* spp. in brassica crops in seasons 2019 and 2020. In summary the disease level of infection in untreated plots was adequate to validate the trials and reliably assess the efficacy of A23109A.

According to EPPO extrapolation Table 14/20176” diseases on vegetable brassicas”, efficacy data against *Peronospora* spp. and *Hyaloperonospora parasitica* on the indicator crops flowerhead brassicas: cauliflower and Romanesco brassica (and lettuce and onion) can be extrapolated to the targeted crops belonging to leafy brassicas: curly kale, kale, leafy brassica, red mustard, pe-tsai under field conditions.

***Peronospora farinosa* f. sp. *spinaciae* on spinach (field)**

Efficacy data for *Peronospora farinosa* f. sp. *spinaciae* on spinach are presented from 5 efficacy trials conducted in EPPO Maritime zone. Assessments were made for pest severity and pest incidence. Results from Belgium, France and The Netherlands obtained over 2 seasons (2019 and 2020) demonstrated that A23109A at the proposed label rate of 0.5 L PR/ha exceeded the efficacy of the commercial standard Infinito. This rate should thus be considered effective against *Peronospora farinosa* f. sp. *spinaciae* on spinach in the Maritime EPPO zone.

The environmental condition experienced in the EPPO maritime zone (mild and wetter) mean than trials data from this zone could be considered a worst case. Claims for *Peronospora farinosa* f. sp. *spinaciae* on spinach thus can be extrapolated from the Maritime data provided to EPPO South-East zone and EPPO North-East zone.

According to EPPO extrapolation Table 14/19578: “Diseases on leafy vegetables”, efficacy data against *Peronospora* spp. on spinach can be extrapolated to the targeted crops: baby leaves, chards and beet leaves, chicory, chives, common purslane, cress, endive, escarole, herbs and edible flowers, lamb's lettuce, parsley, purple-vein rocket, watercress, iceberg lettuce under field conditions.

Interzonal (protected) uses

***Bremia lactucae* on lettuce (Protected)**

At total of 9 protected efficacy trials (assessments: pest incidence and pest severity) from Belgium, France, Italy and Portugal obtained over 2 seasons (2019 and 2020) demonstrated that A23109A at the proposed label rate of 0.5 L PR/ha exceeded the efficacy of the commercial standard Revus. This rate should thus be considered effective against *Bremia lactucae* on lettuce under protected conditions.

According to EPPO extrapolation Table 14/19578: “Diseases on leafy vegetables”, efficacy data against *Bremia lactucae* in lettuce can be extrapolated to the targeted crops: baby leaves, chards and beet leaves, chicory, chives, common purslane, cress, endive, escarole, herbs and edible flowers, lamb's lettuce, parsley, purple-vein rocket, watercress, iceberg lettuce under greenhouse conditions.

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

The unmodified resistance risk for phenylamides (FRAC 4) and OSBPI (FRAC 49) including metalaxyl-

M and oxathiapiprolin should be considered between medium and high depending on the agronomic risk associated to each pathogen/crop system.

The resistance management strategy for A23109A is based on the addition of modifiers such as the limitation of exposure of the pathogen to the fungicide by limiting the number of applications permitted in a program and promoting the use of alternation with products from different MoA cross resistance groups.

- ☐ Applications of A23109A to be applied according to label recommendations and can be made in alternation with products containing different cross-resistance group with satisfactory efficacy against the targeted pathogen(s).
- ☐ Maximum 2 applications A23109A at 0.5 l/ha per crop and per year.
- ☐ Exposure to A23109A should not exceed thirty-three percent (33%) of the total period of protection needed per crop.
- ☐ A23109A applications are to be made preventively.

3.3.2 Adverse effects on treated crops

Phytotoxicity

Zonal (field) uses

Lettuce: A total of 14 open field trials were carried out on lettuce in the EPPO Maritime zone (Belgium, France, Germany) on a wide range of commercially grown varieties.

No phytotoxicity symptom caused by A23109A at the proposed dose rate of 0.5 L/ha was recorded in the efficacy trials. It is anticipated that A23109A will be fully selective, when applied at recommended label rate, for extrapolation to other leafy veg crops (baby leaves, chicory, cress, endive, escarole, herbs & edible flowers, iceberg lettuce, lamb's lettuce, parsley, purple-vein rocket and watercress and as spinach, chards & beet leaves and common purslane).

Onion: 16 trials were carried out on onion in open field conditions in the EPPO Maritime Zone (Belgium, Czech Republic, France, the Netherlands), from 2019 to 2021 on a wide range of commercially grown varieties.

No phytotoxicity symptom caused by A23109A at the proposed dose rate of 0.5 L/ha was recorded in the efficacy trials. It is anticipated that A23109A will be fully selective, when applied at recommended label rate, for extrapolation to other allium (bulb) vegetables as chives, garlic, leek, onion, shallot and spring Welsh and green onion.

Leek: 9 trials were carried out on leek in open field conditions in the EPPO Maritime zone (Belgium, France and the Netherlands) from 2019 to 2020 on a range of commercially grown varieties.

No phytotoxicity symptom caused by A23109A at the proposed dose rate of 0.5 L/ha was recorded in all 9 efficacy trials. It is anticipated that A23109A will be fully selective, when applied at recommended label rate, for extrapolation to other allium (bulb) vegetables as chives, garlic, leek, onion, shallot and spring Welsh and green onion.

Brassicae: 11 trials were carried out on a range of brassica crops in open field conditions in the EPPO Maritime zone (Belgium, Germany, and the Netherlands) from 2019 to 2020 on a range of commercially grown varieties.

No phytotoxicity symptom caused by A23109A at the proposed dose rate of 0.5 L/ha was recorded in all 11 efficacy trials. It is anticipated that A23109A will be fully selective, when applied at recommended label rate, for extrapolation to the whole supported group of brassica crops (broccoli, Brussels sprouts,

cauliflower, curly kale, head cabbage, kale, red mustard, pe-tsai and Savoy cabbage).

Spinach: 5 trials were carried out on spinach in field conditions in Belgium, France and the Netherlands from 2019 to 2020 on a range of commercially grown varieties.

No phytotoxicity symptom caused by A23109A at the proposed dose rate of 0.5 L/ha was recorded in all 5 efficacy trials. It is anticipated that A23109A will be fully selective, when applied at recommended label rate, for all extrapolation to leafy veg crops (baby leaves, chicory, cress, endive, escarole, herbs & edible flowers, iceberg lettuce, lamb's lettuce, parsley, purple-vein rocket and watercress and as spinach, chards & beet leaves and common purslane).

Interzonal (protected) uses

Lettuce:

A total of 11 protected trials (2 selective trials and 9 efficacy trials) were conducted in Belgium, France, Italy, and Portugal from 2019 to 2020 on a wide range of commercially grown varieties.

No phytotoxicity symptom caused by A23109A at the proposed dose rate of 0.5 L/ha was recorded in all 11 trials. It is anticipated that A23109A will be fully selective, when applied at recommended label rate, for extrapolation to other leafy veg crops (baby leaves, chicory, cress, endive, escarole, herbs & edible flowers, iceberg lettuce, lamb's lettuce, parsley, purple-vein rocket and watercress and as spinach, chards & beet leaves and common purslane).

Yield

A23109A appeared fully selective with the supported crops with no symptoms of phytotoxicity therefore no negative effects are expected on yield when A23109A is used as recommended.

No quantitative yield assessments were therefore performed neither in selectivity trials conducted in disease-free conditions nor in efficacy trials conducted in the absence of disease pressure.

Quality

Interzonal (protected) uses

Lettuce (protected): Two trials were carried out in 2020 (Belgium). A23109A was applied at 0.5 and 1 L/ha up to 2 times from BBCH 15 to BBCH 19. The count of marketable plants and the weight of marketable plants was compared to the standard Revus at 0.6 L/ha. A23109A at the proposed registration rate of 0.5 L PR/ha and at 2N rate (1 L PR/ha) gave a quality statistically equivalent compared to the untreated and standard Revus, thus had no negative effects on the quality of lettuce in the absence of the disease.

No unacceptable symptoms caused by the product application were observed during the trials summarized in this dossier. Metalaxyl-M and oxathiapiprolin based products have been and are currently registered and extensively used on target crops (including tomato, lettuce, leek, other bulb vegetables such as onion and garlic, and other minor crops) in some formulation types without report of negative effects since several years.

Taint (leek)

The use of A23109A at proposed label rate and according to good agricultural practice does not lead to any taint on processed leek (frozen). The same conclusion can be also reasonably drawn on other supported crops that could be intended for transformation (including broccoli, cabbage, cauliflower, leek, onion and spinach).

Propagation materials

During years of commercial use of metalaxyl-M or oxathiapiprolin, no negative effects on plant parts

used for propagation have been observed. A23109A has no herbicidal activity and no phytotoxicity or negative impact on quality and yield was recorded. Thus, no data on plant parts for propagation are required.

3.3.3 Observations on other undesirable or unintended side-effects

Succeeding crops: Due to the good selectivity of formulated product A23109A, no negative impacts on succeeding crops can be expected if the product is applied according to good agricultural practice (GAP). Based on this evidence and the risk assessment for non-target terrestrial plants as provided in **Part B, Section 8** (Environmental Fate), it is concluded that the risk to succeeding crops is low.

Adjacent crops: No effects are observed on sensitive crops in field trials, nor in the risk assessment studies for non-target terrestrial plants. It is the applicant's conclusion that A23109A will cause no adverse effects on adjacent crops.

Tank cleaning: A23109A has fungicide activity and no herbicidal activity, therefore the risk from tank residues is of no relevance and no testing of cleaning method are required. However, below recommendations can be included to the product label:

“Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom, and nozzles two to three times with clean water until the foam and all traces of the formulation have been removed.”

Beneficials and non-target: A23109A applied on a wide range of vegetable crops grown in open field and protected trial conditions, did not have negative impact on beneficial insects and non-target organisms. Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarized in **Part B, Section 9** (Ecotoxicology). The principles of the Integrated Pest Management (IPM) seek to identify the safe mixes of chemical and biological controls for a given disease. In compliance with this approach, A23109A is a suitable candidate for inclusion in IPM thanks to its profile and characteristics.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

An analytical method has been developed for the simultaneous determination of oxathiapiprolin and metalaxyl-M (including its S-enantiomer) in A23109A. Full validation of the method SF-1027/2 has been conducted. The method is suitable for the specific and accurate determination of oxathiapiprolin and metalaxyl-M (including its S-enantiomer) in the formulation A23109A.

Analytical method SD-1751/1 has been developed and fully validated for the determination of the metalaxyl-M relevant impurities CGA72649 and CGA363736 in A23109A. The method is suitable for the specific, accurate and precise determination of CGA72649 and CGA363736 in product A23109A.

The analytical method SD-2790/1 has been developed and fully validated for the determination of the relevant impurity **CGA226048** (consists of CGA226048 diastereomer A and CGA226048 diastereomer B) in A23109A using standard addition sample preparation coupled with liquid chromatography with mass spectrometry detection.

~~Impurity 2 [(2,6-dimethyl-phenyl)-(2-methoxyacetyl)-amino]-propionic acid-1-methoxycarbonyl-ethyl ester (coded CGA226048) was considered as non-relevant at the time of submission, due to ongoing discussions on EU level (EFSA). In case this impurity is considered as relevant, the availability of a validated method is considered as a data requirement. However as the discussion on the impurities on EU level is still ongoing the analytical method for impurity should be available. According to the information provided by the applicant on the ZRMS request, the relevant analytical method for CGA226048 is under development.~~

There are no relevant formulants in A23109A therefore no methods are required.

There is no CIPAC method available for the determination of metalaxyl-M or oxathiapiprolin.

3.4.2 Analytical methods for residues

Pre- and post-authorisation analytical methods for metalaxyl-M and oxathiapiprolin are available to address data provided in support of the crop groups applied for. The analytical methods provided also address the components of the residue definition as relevant.

A number have been reviewed in the EU and further methods, validations and ILVs have been provided where necessary. All data are considered acceptable.

Metalaxyl-M

EFSA concluded in EFSA Journal 2015;13(3):3999 – “Peer review of the pesticide risk assessment of the active substance metalaxyl-M” that *“The compounds in the residue definition for plants can be determined with a multi-residue method (QuEChERS) however a data gap was identified for extraction efficiency. Analytical methods for food of animal origin are not required in this regulatory context as there is no significant intake by livestock, when solely considering the supported representative uses. LC-MS/MS (liquid chromatography with tandem mass spectrometry) methods are available to monitor the compounds in the residue definitions for water, soil and air.*

The active substance is not classified as a Health Hazard under CLP and therefore a method of analysis is not required for body fluids and tissues.”

The Applicant submitted a number of methods for analysis of residues of azoxystrobin for the generation of pre-authorization data and methods for post-authorization control and monitoring purposes.

The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

Oxathiapiprolin

EFSA concluded in EFSA Journal 2016;14(7):4504 - “Peer review of the pesticide risk assessment of the active substance oxathiapiprolin” that: *Oxathiapiprolin residues can be monitored in food and feed of plant origin by the multi-residue method DFG S19 using LC-MS/MS in dry, high water content and acidic matrices with limits of quantification (LOQs) of 0.01 mg/kg, or by a single HPLC-MS/MS method with LOQs of 0.01 mg/kg for all plant commodity groups. Residues of oxathiapiprolin in food of animal origin can be monitored with the multi-residue method DFG S19 using LC-MS/MS in meat, fat, liver, milk and eggs with LOQs of 0.01 mg/kg or by a single HPLC-MS/MS method with LOQs of 0.01 mg/kg for all animal matrices.*

Residues of oxathiapiprolin in soil, water and air can be monitored by LC-MS/MS with LOQs of 1 µg/kg, 0.1 µg/L and 0.05 µg/m³, respectively.

No analytical method is required for the determination of oxathiapiprolin in body fluids and tissues as oxathiapiprolin is not classified as toxic or very toxic.

The Applicant submitted a number of methods for analysis of residues of oxathiapiprolin for the generation of pre-authorization data and methods for post-authorization control and monitoring purposes.

The details of the evaluation of new and additional studies are referred in Appendix 2 of Part B5.

Applicant submitted additional information:

The Applicant would like to highlight that the Technical Guideline on the Evaluation of Extraction Efficiency, SANTE/2017/10632, states that ‘for renewal of product authorisations or for new product authorisations or extension of uses for which no change of the MRL is needed, the data requirements used for the latest renewal or approval should be considered. This means that no additional proof of extraction efficiency is required if it had not been required in the renewal of approval/approval procedure itself.’ Both oxathiapiprolin and metalaxyl-M were last renewed prior to the implementation of the extraction efficiency guideline SANTE/2017/10632 (implementation date: 23 Nov 2019) and, hence, an assessment of extraction efficiency was not required during the renewal, the demonstration of extraction efficiency is

not required to support this product submission.

No additional data is required to support this application.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

A summary of the toxicological evaluation for A23109A is given in the following table:

Type of test, species, model system (Guideline)	Result	ATE & Additivity Calculation Result	Acceptability	Classification ¹ (acc. to the criteria in Reg. 1272/2008)
LD ₅₀ oral, rat (OECD 425)	> 2000 mg/kg bw	>2000 mg/kg Not classified	Yes	None
LD ₅₀ dermal, rat (OECD 402)	>2000 mg/kg bw	>2000 mg/kg Not classified	Yes	None
LC ₅₀ inhalation, rat (OECD 403)	> 5.46 mg/L air	> 5.0 mg/L Not classified	Yes	None
Skin irritation, <i>in vitro</i> (OECD 439)	Non-irritant	n/a Not classified	No	None
Skin irritation, rabbit (OECD 404)	Non-irritant	n/a Not classified	Yes	None
Eye irritation, rabbit (OECD 405)	Moderate irritant Category 2	Eye irritant Category 1	Yes	H319 ^{1, 2}
Skin sensitisation, Mouse (OECD 429, LLNA)	Sensitising Category 1B	n/a Not classified	Yes	H317 ¹
Supplementary studies for combinations of plant protection products	No data – not required	No data – not required		-

¹ Proposed acute toxicity classifications are based on A23109A study results.

²: Differences in hazard statements may arise between the B.6 and the SDS, due to the difference in Regulation (EC) No 1272/2008 and the GHS for classification.

Since that the provisions of Regulation 1272/2008 indicate that the *in vivo* tests are overriding the estimation of the calculation method (ATE, Additivity method) also due to fact that mentioned above *in vitro* tests (e.g. OECD 439 is not suitable for agrochemical, see detailed comment in the Preface dRR Section B6 p.5), ZRMS PL decided to summarize assessment of toxicological hazards for A23109A considering available *in vivo* tests. (for details refer Section B6)

Data and toxicological studies on metalaxyl-M metabolites NOA409045, SYN546520 and CGA67868 and oxathiapiprolin metabolite IN-E8S72, with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment, are submitted and evaluated in the dRR Section B6 referring to genotoxicity potential of the mentioned above metabolites.

The relevance assessment of the metabolites is reported in Part B.10.

3.5.2 Operator exposure

Zonal (field) uses

Operator exposure for zonal, field use of A23109A was modelled using EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection product [EFSA Journal 2014;12(10):3874 (55pp.)].

According to the exposure calculations, it can be concluded that the risk for the operator using A23109A on a range of outdoor crops is acceptable with the use of personal protective equipment (e.g. a coverall as

usual work wear), and in addition impermeable gloves when mixing and loading, and during application for handheld manual and knapsack spray applications to low crops.

Interzonal (protected) uses

Operator exposure for interzonal, protected use of A23109A was modelled using ~~the Dutch Green House model [Dutch model for manual application in glasshouses, van Hemmen, 1992; van Golstein Brouwers et al., 1996; Snippe R J et al., 2002] and the Southern European Glasshouse Model [Greenhouse model v_2.1 (20101223) with Southern European Greenhouse Model Overview. Members of the European Crop Protection Association. Occupational & Bystander Exposure Expert Group. October 2010 (Revision 9). ECPA, European Crop Protection Association, aisbl 6, Avenue E. Van Nieuwenhuyse, B-1160 Brussels, Belgium.]~~ EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection products [EFSA Journal 2022;20(1):7032].

According to the exposure calculations, it can be concluded that the risk for the operator using A23109A on a range of protected crops ~~during the intensive crop scenario~~ is acceptable with the use of personal protective equipment (impermeable coveralls for ~~the mixing and loading, and during application~~). Additionally, due to the innate hazard of the formulation operators are required to wear protective gloves, protective clothing, eye protection and face protection.

3.5.3 Worker exposure

Zonal (field) uses

Worker exposure for A23109A was modelled using EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection product [EFSA Journal 2014;12(10):3874 (55pp.)].

According to the exposure calculations, it can be concluded that the risk for the worker from A23109A on a range of crops is anticipated to be acceptable with no PPE.

Interzonal (protected) uses

Operator exposure for interzonal, protected use of A23109A was modelled using ~~the Dutch Green House model [Dutch model for manual application in glasshouses, van Hemmen, 1992; van Golstein Brouwers et al., 1996; Snippe R J et al., 2002] and the Southern European Glasshouse Model [Greenhouse model v_2.1 (20101223) with Southern European Greenhouse Model Overview. Members of the European Crop Protection Association. Occupational & Bystander Exposure Expert Group. October 2010 (Revision 9). ECPA, European Crop Protection Association, aisbl 6, Avenue E. Van Nieuwenhuyse, B-1160 Brussels, Belgium.]~~ EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection products [EFSA Journal 2022;20(1):7032].

According to the exposure calculations, it can be concluded that the risk for the ~~operator using~~ worker from A23109A on a range of protected crops is acceptable with ~~the use of normal personal protective equipment (impermeable coveralls for the application)~~ only no PPE.

3.5.4 Bystander and resident exposure

Zonal (field) uses

According to EC guidance document SANTE-10832-2015, the (EFSA Guidance) risk assessment on residents and bystanders cannot be fully considered until a procedure for the derivation of the AAOEL and higher risk assessment schemes, identified as missing by the Standing Committee, are available.

Consequently, this evaluation provides a first tier assessment based on the EFSA guidance for longer term exposures to residents' only, using 75th percentile data and comparing with the relevant AOEL. This assessment is equally applicable to longer term exposures for bystanders.

Bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for metalaxyl-M and oxathiapiprolin will not be exceeded under conditions of

intended uses.

Interzonal (protected) uses

~~A23109A is to be applied in greenhouses. Therefore, bystander / resident exposure is normally considered to be negligible.~~ is intended to be applied in protected structures, such as greenhouses. Exposure to resident and bystanders outside the spray event is expected to be negligible. However, according to the EFSA Guidance on the assessment of exposure of operators, workers, resident and bystanders in risk assessment for plant protection products [EFSA Journal 2022;20(1):7032], exposure calculations are required to estimate the resident and bystander exposure from applications covering protected structures. The use of field data as a surrogate for exposure following indoor spraying, as per dictated by the EFSA guidance 2022, can be considered as overly conservative. Nevertheless, in aiming to meet the regulatory requirement as stipulated by the EFSA Guidance, the applicant proposes a more pragmatic approach that leverages existing risk assessment mitigation measures available to resident and bystander routes of exposure to better represent the reduced risk from applying PPPs under protected conditions:

- Use of 50% drift reduction technology (DRT) as standard in protected risk assessment
- ~~10 m buffer zone~~

zRMS comment (April 2024)

- 10 m buffer zone: given the geographic positioning and physical structure separation anticipated between spray operator and any resident/bystander, it is unrealistic for protected structure exposure to occur just 2 or 3 meters from the sprayer. The use of a 10-meter buffer zone would result in a more representative resident and bystander exposure.

According to the exposure calculations, it can be concluded that the risk to bystander and/or resident from A23109A is acceptable under the conditions of intended uses.

Combined Exposure and Risk Assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised ‘scientific methods accepted by the Authority to assess such effects are available.’

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances.

Zonal (field) uses

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

The Hazard Index is not expected to present a risk for workers, residents and bystanders following combined exposure to all active substances in A23109A, since the value is < 1 . Thus, no further refinement of the assessment is required.

However, the Hazard Index is > 1 for operators applying ORONDIS VIP manually, for which refinement of the assessment is required. Further refinement in the form using gloves during mixing and loading, as well as application, will lower the Hazard Index < 1 . Additionally, since this formulation is a sensitizer the use of gloves is considered an obligatory requirement.

Interzonal (protected) uses

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

The Hazard Index is < 1 for operators, workers and residents with the exception of Operators for the

“dense” foliage scenario. This scenario was assessed as part of the new EFSA model (EFSA 2022) and included for completeness, however the dense scenario is not realistic for the assessed use (i.e. baby leaves, BBCH 12-49). The EFSA guidance defines Dense Crop as “Crops (high or low) for which the spray operator technically cannot avoid contact with the treated foliage during spray operations” and this is not the case for cultivation to baby leaves. Therefore the dense scenario is not considered as part of the assessment and the ~~Thus~~ combined exposure to all active substances in A23109A, is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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

3.6.1 Residues

Zonal (field) uses

Metalaxyl-M

The residues arising from the proposed uses: garlic, onion, shallots, spring onion, green onion, welsh onion, broccoli, brussels sprout, head cabbage, savoy cabbage, kale and curly kale, lamb’s lettuce, lettuce (open leaf), iceberg lettuce, escarole, cress, rocket, red mustard, baby leaf, spinach, common purslane, chards and beet leaves, chicory / endive, herbs and edible flowers, parsley, chives, leek except pe-tsai and watercress will not exceed the MRLs established for metalaxyl-M in Reg. (EU) 2017/1164. These uses are considered acceptable.

Considering the intended use on Chinese cabbage/pet-tsai and watercress, an exceedance of the MRLs for metalaxyl-M, as established in Reg. (EU) 2017/1164 is expected. Therefore until the new MRLs for Chinese cabbage/pet-tsai and watercress come into force, authorization of the GAP will not be possible.

The proposed uses on Chinese cabbage/pet-tsai and watercress are not considered acceptable.

The effects of processing on the nature of metalaxyl-M residues have been investigated. Data on effects of processing on the amount of residue have been submitted. Metalaxyl-M is hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No chronic and acute risk for the consumer is identified.

Oxathiapiprolin

The residues arising from the following proposed uses: garlic, onion, shallots, spring onion, green onion, welsh onion, broccoli, brussels sprout, head cabbage, savoy cabbage, Chinese cabbage/pet-tsai, lamb’s lettuce, lettuce (open leaf), iceberg lettuce, escarole, cress, rocket, red mustard, baby leaf, spinach, common purslane, chards and beet leaves, chicory / endive, leek, basil and edible flowers (0256080) will not exceed the MRLs established for oxathiapiprolin in Reg. (EU) 2023/163. These uses are considered acceptable.

Considering the intended uses on kale and curly kale, herbs and edible flowers (0256000) except basil and edible flowers (0256080), chives, parsley and watercress, an exceedance of the MRLs for oxathiapiprolin, as established in Reg. (EU) 2023/163 is expected. Therefore until the new MRLs for these crops come into force, authorization of the GAP will not be possible.

The proposed uses on kale and curly kale, herbs and edible flowers (0256000) except basil and edible flowers (0256080), chives, parsley and watercress are not considered acceptable.

The nature and magnitude of residues in processed commodities relevant to these crops were evaluated in the Oxathiapiprolin Draft Assessment Report, Volume 3, CA, Annex B.7 (2016) and by Ireland (EFSA, 2019). These studies showed that oxathiapiprolin is hydrolytically stable under standard processing conditions. The processing studies are not expected to significantly affect the consumer risk assessment.

Considering the livestock dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

The nature and magnitude of residues in rotational crop commodities were evaluated in the Oxathiapiprolin Draft Assessment Report, Volume 3, Annex B7, Residue Data (2016). According the Conclusion on the peer review of the pesticide risk assessment of the active substance oxathiapiprolin. EFSA Journal 2016;14(7):4504, 19 pp. (European Food Safety Authority), 2016, numerous field rotational crop studies were submitted to confirm that residues of pyrazole metabolites (IN-SXS67 and IN-E8S72) are not expected to be detected in significant levels in rotational crops when the active substance is applied at a maximum seasonal application rate of 90 g/ha, therefore residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

The chronic and the short-term intakes of oxathiapiprolin residues are unlikely to present a public health concern.

Interzonal (protected) uses

Metalaxyl-M

The residues arising from the proposed uses: baby leaf [251080], chicory / endive [255000], cress [254000], escarole [251030], lamb's lettuce [251010], lettuce [251020], purple-vein rocket [251060] except watercress [254000] will not exceed the MRLs established for metalaxyl-M in Reg. (EU) 2017/1164. These uses are considered acceptable.

Considering the intended use on watercress, an exceedance of the MRL for metalaxyl-M, as established in Reg. (EU) 2017/1164 is expected. Therefore until the new MRL for watercress comes into force, authorization of the GAP will not be possible.

The proposed use on watercress is not considered acceptable.

The effects of processing on the nature of metalaxyl-M residues have been investigated. Data on effects of processing on the amount of residue have been submitted. Metalaxyl-M is hydrolytically stable under the representative processing conditions and the same residue definitions as for raw agricultural commodities apply.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No chronic and acute risk for the consumer is identified.

Oxathiapiprolin

The residues arising from the proposed uses will not exceed the MRLs established for oxathiapiprolin for lettuces and salad plants of 5 mg/kg in Reg. (EU) 2023/163. The uses are considered acceptable.

Considering the intended use on watercress, an exceedance of the MRL for oxathiapiprolin, as established in Commission Regulation (EU) 2023/163 (0.01 mg/kg*) is expected. Therefore until the new MRL for watercress come into force, authorization of the GAP will not be possible. The proposed use on watercress is not considered acceptable.

The nature and magnitude of residues in processed commodities relevant to these crops were evaluated in the Oxathiapiprolin Draft Assessment Report, Volume 3, CA, Annex B.7 (2016) and by Ireland (EFSA, 2019). These studies showed that oxathiapiprolin is hydrolytically stable under standard processing conditions. The processing studies are not expected to significantly affect the consumer risk assessment.

Considering the livestock dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

The nature and magnitude of residues in rotational crop commodities were evaluated in the Oxathiapiprolin Draft Assessment Report, Volume 3, Annex B7, Residue Data (2016). According the Conclusion on the peer review of the pesticide risk assessment of the active substance oxathiapiprolin. EFSA Journal 2016;14(7):4504, 19 pp. (European Food Safety Authority), 2016, numerous field rotational crop studies were submitted to confirm that residues of pyrazole metabolites (IN-SXS67 and IN-E8S72) are not expected to be detected in significant levels in rotational crops when the active substance is applied at a maximum seasonal application rate of 90 g/ha, therefore residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

The chronic and the short-term intakes of oxathiapiprolin residues are unlikely to present a public health concern.

3.6.2 Consumer exposure

Metalaxyl-M

TMDI (% ADI) according to EFSA PRIMo 3.1	31% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not required as TMDI < 100%
<u>Zonal (field) uses</u>	
IESTI RAC (% ARfD) according to EFSA PRIMo*	Escaroles/broad-leaved endives :2% (based on BE toddler) Lettuces : 2 % (based on NL child)
IESTI Processed (% ARfD) according to EFSA PRIMo*	Escaroles/broad-leaved endives / boiled : 4% (based on NL toddler) Chards/beet leaves / boiled : 2% (based on NL child)
<u>Interzonal (protected) uses</u>	
IESTI RAC (% ARfD) according to EFSA PRIMo*	Escaroles/broad-leaved endives :1% (based on BE toddler) Witloofs/Belgian endives : 1% (based on BE toddler)
IESTI Processed (% ARfD) according to EFSA PRIMo*	Escaroles/broad-leaved endives boiled :2% (based on NL toddler) Endives boiled : 2% (based on NL toddler)

The proposed uses of metalaxyl-M in the A23109A do not represent unacceptable acute or chronic risks for the consumer.

Oxathiapiprolin

Zonal (field) uses & Interzonal (protected) uses	
TMDI (% ADI) according to EFSA PRIMo 3.1	±± 12% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not calculated as TMDI passes
TESTI RAC (% ARfD) according to EFSA PRIMo*	Not applicable (no ARfD set)
TESTI Processed (% ARfD) according to EFSA PRIMo*	Not applicable (no ARfD)

The proposed uses of oxathiapiprolin in A23109A do not represent unacceptable chronic risks for the consumer.

Combined Exposure and Risk Assessment

Not relevant.

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

Additional active substance data submitted by the applicant were considered by zRMS/izRMS as necessary for authorisation. Therefore, according to SANCO/10328/2004 – rev 9 (21.10.2021) point 4.3.1/2, zRMS used it for the groundwater risk assessment.

The PEC calculation performed for leafy vegetables cover uses in broccoli, baby leaves, cauliflower, chicory, escarole, lettuce, herbs, edible flowers etc.

The PEC calculation performed for onions cover uses in leek, garlic, shallot etc.

Metalaxyl-M

Studies on the aerobic and anaerobic degradation rates of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 are considered to be data provided in support of the active substance. Unless otherwise stated, relevant detailed experimental information has been submitted for EU review of metalaxyl-M (EFSA Journal 2015; 13(3):3999).

Additional information on the degradation of metabolite SYN546520 is detailed in Part B Section 8, Appendix 3.

Studies on the field dissipation rates of metalaxyl-M and its metabolite NOA409045 are considered to be data provided in support of the active substance. Unless otherwise stated, relevant detailed experimental information has been submitted for EU review of metalaxyl-M (EFSA Journal 2015; 13(3):3999).

Studies on the mobility of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 in soil are considered to be data provided in support of the active substance. Unless otherwise stated, relevant detailed experimental information has been submitted for EU review of metalaxyl-M (EFSA Journal 2015; 13(3):3999).

Where performed, column leaching, lysimeter, field leaching studies and studies on the degradation in water/sediment systems are considered to be data provided in support of the active substance. Unless otherwise stated, relevant detailed experimental information has been submitted for EU review of metalaxyl-M (EFSA Journal 2015; 13(3):3999).

Oxathiapiprolin

Studies on the aerobic and anaerobic degradation rates of oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 are considered to be data provided in support of the active substance. Unless otherwise stated, relevant detailed experimental information has been submitted for EU review of oxathiapiprolin (EFSA Journal 2016; 14(7):4504).

Studies on the field dissipation rates of oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06 and

IN-E8S72 are considered to be data provided in support of the active substance. Unless otherwise stated, relevant detailed experimental information has been submitted for EU review of oxathiapiprolin (**EFSA Journal 2016; 14(7):4504**).

Studies on the mobility of oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10, and IN-E8S72 in soil are considered to be data provided in support of the active substance. Unless otherwise stated, relevant detailed experimental information has been submitted for EU review of oxathiapiprolin (**EFSA Journal 2016; 14(7):4504**).

Where performed, column leaching, lysimeter, field leaching studies and studies on the degradation in water/sediment systems are considered to be data provided in support of the active substance. Unless otherwise stated, relevant detailed experimental information has been submitted for EU review of oxathiapiprolin (**EFSA Journal 2016; 14(7):4504**).

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

Zonal (field) uses

Metalaxyl-M

Predicted Environmental Concentrations of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 in soil (PEC_s) listed below are detailed in Part B Section 8 of this submission.

PEC_s for metalaxyl-M

The PEC_s of metalaxyl-M has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT₅₀ value established in the EU review (**EFSA Journal 2015; 13(3):3999**). Based on the recommended use rate of 2×87.2 g a.s./ha to bulb vegetables or leafy vegetables, the maximum initial Predicted Environmental Concentration in soil (PEC_{s,ini}) of metalaxyl-M was 0.1941 mg/kg.

In addition to the seasonal PEC_{s,ini} calculations, the potential accumulation (PEC_{s,accumulation}) of metalaxyl-M in soil following repeated applications of A23109A to bulb vegetables or leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration (PEC_{s,plateau}) of <0.0001 mg/kg would be reached after many years. The long term Predicted Environmental Concentration (PEC_{s,accumulation}) was calculated as 0.1941 mg/kg.

PEC_s for NOA409045

The PEC_s of NOA409045 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT₅₀ value established in the EU review (**EFSA Journal 2015; 13(3):3999**). For NOA409045 the proposed use pattern will lead to maximum PEC_{s,ini} of 0.1349 mg/kg.

In addition to the seasonal PEC_{s,ini} calculations, the potential accumulation (PEC_{s,accumulation}) of NOA409045 in soil following repeated applications of A23109A to bulb vegetables or leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration (PEC_{s,plateau}) of 0.0001 mg/kg would be reached after many years. The long term Predicted Environmental Concentration (PEC_{s,accumulation}) was calculated as 0.1350 mg/kg.

PEC_s for CGA67868

The PEC_s of CGA67868 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT₅₀ value established in the EU review (**EFSA Journal 2015; 13(3):3999**). For CGA67868 the proposed use pattern will lead to maximum PEC_{s,ini} of 0.0060 mg/kg.

In addition to the seasonal PEC_{s,ini} calculations, the potential accumulation (PEC_{s,accumulation}) of CGA67868 in soil following repeated applications of A23109A to bulb vegetables or leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration (PEC_{s,plateau}) of < 0.0001 mg/kg would be reached after many years.

The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0060 mg/kg.

PEC_S for SYN546520

The PEC_S of SYN546520 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (**EFSA Journal 2015; 13(3):3999**). For SYN546520 the proposed use pattern will lead to maximum $PEC_{S,ini}$ of 0.0088 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of SYN546520 in soil following repeated applications of A23109A to bulb vegetables or leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of 0.0016 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0103 mg/kg.

Oxathiapiprolin

Predicted Environmental Concentrations of oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 in soil (PEC_S) listed below are detailed in Part B Section 8 of this submission.

PEC_S for oxathiapiprolin

The PEC_S of oxathiapiprolin has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (**EFSA Journal 2016; 14(7):4504**). Based on the recommended use rate of 2×15 g a.s./ha to bulb vegetables or leafy vegetables, the maximum initial Predicted Environmental Concentration in soil ($PEC_{S,ini}$) of oxathiapiprolin was 0.0356 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of oxathiapiprolin in soil following repeated applications of A23109A to bulb vegetables or leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of 0.0037 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0392 mg/kg.

PEC_S for IN-RDT31

The PEC_S of IN-RDT31 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (**EFSA Journal 2016; 14(7):4504**). For IN-RDT31 the proposed use pattern will lead to maximum $PEC_{S,ini}$ of 0.0032 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of IN-RDT31 in soil following repeated applications of A23109A to bulb vegetables or leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of 0.0031 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0063 mg/kg.

PEC_S for IN-RAB06

The PEC_S of IN-RAB06 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (**EFSA Journal 2016; 14(7):4504**). For IN-RAB06 the proposed use pattern will lead to maximum $PEC_{S,ini}$ of 0.0051 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of IN-RAB06 in soil following repeated applications of A23109A to bulb vegetables or leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of 0.0004 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0054 mg/kg.

PEC_S for IN-QPS10

The PEC_S of IN-QPS10 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (**EFSA Journal 2016; 14(7):4504**). For IN-QPS10 the proposed use pattern will lead to maximum $PEC_{S,ini}$ of 0.0016 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of IN-QPS10 in soil following repeated applications of A23109A to bulb vegetables or leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of 0.0009 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0025 mg/kg.

PEC_S for IN-E8S72

The PEC_S of IN-E8S72 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (EFSA Journal 2016; 14(7):4504). For IN-E8S72 the proposed use pattern will lead to maximum $PEC_{S,ini}$ of 0.0012 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of IN-E8S72 in soil following repeated applications of A23109A to bulb vegetables or leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of 0.0004 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0017 mg/kg.

PEC_S for A23109A on bulb vegetables or leafy vegetables

The PEC_S of A23109A has been assessed with the FOCUS groundwater crop interception values. Based on the recommended use rate of 0.5 L p.p.p./ha (537 g p.p.p./ha), the maximum initial Predicted Environmental Concentration in soil (PEC_S) of A23109A will be 0.644 mg/kg.

The results for PEC_S calculations are used in the Ecotox risk assessment, as detailed in Part B Section 9 of this submission.

Interzonal (protected) uses

Metalaxyl-M

Predicted Environmental Concentrations of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 in soil (PEC_S) listed below are detailed in Part B Section 8 of this submission.

PEC_S for metalaxyl-M

The PEC_S of metalaxyl-M has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (EFSA Journal 2015; 13(3):3999). As a first tier, calculations were conducted as for field applications. Based on the recommended use rate of 2×87.2 g a.s./ha to leafy vegetables, the maximum initial Predicted Environmental Concentration in soil ($PEC_{S,ini}$) of metalaxyl-M was 0.1617 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of metalaxyl-M in soil following repeated applications of A23109A to leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of < 0.0001 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.1617 mg/kg.

PEC_S for NOA409045

The PEC_S of NOA409045 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (EFSA Journal 2015; 13(3):3999). As a first tier, calculations were conducted as for field applications. For NOA409045 the proposed use pattern will lead to maximum $PEC_{S,ini}$ of 0.1124 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of NOA409045 in soil following repeated applications of A23109A to leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of < 0.0001 mg/kg would be reached after many years. The long term

Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.1125 mg/kg.

PEC_S for CGA67868

The PEC_S of CGA67868 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (EFSA Journal 2015; 13(3):3999). As a first tier, calculations were conducted as for field applications. For CGA67868 the proposed use pattern will lead to maximum $PEC_{S,ini}$ of 0.0050 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of CGA67868 in soil following repeated applications of A23109A to leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of < 0.0001 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0050 mg/kg.

PEC_S for SYN546520

The PEC_S of SYN546520 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (EFSA Journal 2015; 13(3):3999). As a first tier, calculations were conducted as for field applications. For SYN546520 the proposed use pattern will lead to maximum $PEC_{S,ini}$ of 0.0073 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of SYN546520 in soil following repeated applications of A23109A to leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of 0.0013 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0086 mg/kg.

Oxathiapiprolin

Predicted Environmental Concentrations of oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 in soil (PEC_S) listed below are detailed in Part B Section 8 of this submission.

PEC_S for oxathiapiprolin

The PEC_S of oxathiapiprolin has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (EFSA Journal 2016; 14(7):4504). As a first tier, calculations were conducted as for field applications. Based on the recommended use rate of 2×15 g a.s./ha to leafy vegetables, the maximum initial Predicted Environmental Concentration in soil ($PEC_{S,ini}$) of oxathiapiprolin was 0.0296 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of oxathiapiprolin in soil following repeated applications of A23109A to leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of 0.0031 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0327 mg/kg.

PEC_S for IN-RDT31

The PEC_S of IN-RDT31 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (EFSA Journal 2016; 14(7):4504). As a first tier, calculations were conducted as for field applications. For IN-RDT31 the proposed use pattern will lead to maximum $PEC_{S,ini}$ of 0.0027 mg/kg.

In addition to the seasonal $PEC_{S,ini}$ calculations, the potential accumulation ($PEC_{S,accumulation}$) of IN-RDT31 in soil following repeated applications of A23109A to leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration ($PEC_{S,plateau}$) of 0.0026 mg/kg would be reached after many years. The long term Predicted Environmental Concentration ($PEC_{S,accumulation}$) was calculated as 0.0053 mg/kg.

PEC_s for IN-RAB06

The PEC_s of IN-RAB06 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT₅₀ value established in the EU review (EFSA Journal 2016; 14(7):4504). As a first tier, calculations were conducted as for field applications. For IN-RAB06 the proposed use pattern will lead to maximum PEC_{s,ini} of 0.0042 mg/kg.

In addition to the seasonal PEC_{s,ini} calculations, the potential accumulation (PEC_{s,accumulation}) of IN-RAB06 in soil following repeated applications of A23109A to leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration (PEC_{s,plateau}) of 0.0003 mg/kg would be reached after many years. The long term Predicted Environmental Concentration (PEC_{s,accumulation}) was calculated as 0.0045 mg/kg.

PEC_s for IN-QPS10

The PEC_s of IN-QPS10 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT₅₀ value established in the EU review (EFSA Journal 2016; 14(7):4504). As a first tier, calculations were conducted as for field applications. For IN-QPS10 the proposed use pattern will lead to maximum PEC_{s,ini} of 0.0014 mg/kg.

In addition to the seasonal PEC_{s,ini} calculations, the potential accumulation (PEC_{s,accumulation}) of IN-QPS10 in soil following repeated applications of A23109A to leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration (PEC_{s,plateau}) of 0.0007 mg/kg would be reached after many years. The long term Predicted Environmental Concentration (PEC_{s,accumulation}) was calculated as 0.0021 mg/kg.

PEC_s for IN-E8S72

The PEC_s of IN-E8S72 has been assessed with the ESCAPE v2.0 model, FOCUS groundwater crop interception values and the worst case DT₅₀ value established in the EU review (EFSA Journal 2016; 14(7):4504). As a first tier, calculations were conducted as for field applications. For IN-E8S72 the proposed use pattern will lead to maximum PEC_{s,ini} of 0.0010 mg/kg.

In addition to the seasonal PEC_{s,ini} calculations, the potential accumulation (PEC_{s,accumulation}) of IN-E8S72 in soil following repeated applications of A23109A to leafy vegetables was calculated. Assuming the same application regime is used year after year as a worst case, it was predicted that a plateau concentration (PEC_{s,plateau}) of 0.0004 mg/kg would be reached after many years. The long term Predicted Environmental Concentration (PEC_{s,accumulation}) was calculated as 0.0014 mg/kg.

PEC_s for A23109A on leafy vegetables

The PEC_s of A23109A in has been assessed with the FOCUS groundwater crop interception values. Based on the recommended use rate of 0.5 L p.p.p./ha (537 g p.p.p./ha), the maximum initial Predicted Environmental Concentration in soil (PEC_s) of A23109A will be 0.537 mg/kg.

The results for PEC_s calculations are used in the Ecotox risk assessment, as detailed in Part B Section 9 of this submission.

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

Zonal (field) uses

Metalaxyl-M

Groundwater modelling on metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 has not been previously reviewed at an EU level, and is provided in support of this assessment in Part B Section 8, Appendix 3.

The Predicted Environmental Concentration of metalaxyl-M and soil metabolites NOA409045, CGA67868 and SYN546520 in ground water (PEC_{GW}) has been assessed with the standard FOCUS

scenarios, the FOCUS PEARL v5.5.5., FOCUS PELMO v6.6.4 and MACRO v5.5.4 models, and using endpoints established in the EU review (**EFSA Journal 2015; 13(3):3999**) or, for metabolite SYN546520, proposed in data points KCP 9.1.1 based on new calculations/data provided for this assessment.

The PEC_{GW} of metalaxyl-M at 1m depth following 20 years use on bulb vegetables or leafy vegetables at 2×87.2 g a.s./ha from growth state of BBCH 12 and 10-25% foliar interception, was less than 0.1 μ g/L in all scenarios. The potential for the metabolites NOA409045, CGA67868 and SYN546520 to leach to ground water has been assessed using the same approach.

The maximum PEC_{GW} of NOA409045 was ~~6.666~~ 9.163 μ g/L, however an assessment concluding the non-relevance of NOA409045 in groundwater is presented in the Part B Section 10 of this submission. The assessment of metabolite NOA409045 is crucial for the authorisation process. Therefore further refinement and toxicological data are required. For the conclusions of the evaluation please refer to Part B Section 10.

The maximum PEC_{GW} of CGA67868 was ~~0.194~~ 0.267 μ g/L, however an assessment concluding the non-relevance of CGA67868 in groundwater is presented in the Part B Section 10 of this submission.

The maximum PEC_{GW} of SYN546520 was either 15.462 μ g/L (Tier 1) or 3.489 μ g/L (Tier 2), however an assessment concluding the non-relevance of SYN546520 in groundwater is presented in the Part B Section 10 of this submission.

~~Based on the assessment~~ If the groundwater metabolite NOA409045 will be consider as not relevant in Section B10, the use of metalaxyl-M, ~~is not expected to lead to leaching into groundwater at levels that would be unacceptable when~~ applied according to the recommended use pattern, will be acceptable.

Oxathiapiprolin

Groundwater modelling on oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 has not been previously reviewed at an EU level, and is provided in support of this assessment in Part B Section 8, Appendix 3.

The Predicted Environmental Concentration of oxathiapiprolin and soil metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 in ground water (PEC_{GW}) has been assessed with the standard FOCUS scenarios, the FOCUS PEARL v5.5.5., FOCUS PELMO v6.6.4 and MACRO v5.5.4 models, and using endpoints established in the EU review (**EFSA Journal 2016; 14(7):4504**).

The PEC_{GW} of oxathiapiprolin at 1m depth following 20 years use on bulb vegetables or leafy vegetables at 2×15 g a.s./ha from growth state of BBCH 12 and 10-25% foliar interception, was less than 0.1 μ g/L in all scenarios. The potential for the metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 to leach to ground water has been assessed using the same approach.

The PEC_{GW} of IN-RDT31 was less than 0.1 μ g/L in all scenarios.

The PEC_{GW} of IN-RAB06 was less than 0.1 μ g/L in all scenarios.

The PEC_{GW} of IN-QPS10 was less than 0.1 μ g/L in all scenarios.

The maximum PEC_{GW} of IN-E8S72 was 2.238 μ g/L, however an assessment concluding the non-relevance of IN-E8S72 in groundwater is presented in the Part B Section 10 of this submission.

Based on the assessment, the use of oxathiapiprolin is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

Interzonal (protected) uses

Metalaxyl-M

Groundwater modelling on metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 has not been previously reviewed at an EU level, and is provided in support of this assessment in Part B Section 8, Appendix 3.

The Predicted Environmental Concentration of metalaxyl-M and soil metabolites NOA409045, CGA67868 and SYN546520 in ground water (PEC_{GW}) has been assessed with the standard FOCUS scenarios, the FOCUS PEARL v5.5.5., FOCUS PELMO v6.6.4 and MACRO v5.5.4 models, and using endpoints established in the EU review (EFSA Journal 2015; 13(3):3999) ~~for CZ uses and endpoints calculated based on the recommendations in the latest guideline (EFSA, 2014) for SZ uses, or, for metabolite SYN546520, proposed in data points KCP 9.1.1 based on new calculations/data provided for this assessment. The individual values from which the endpoints were calculated are those established in the EU review.~~

The PEC_{GW} of metalaxyl-M at 1m depth following 20 years use on leafy vegetables at 2 × 87.2 g a.s./ha from growth state of BBCH 12 and 25% foliar interception, was less than 0.1 µg/L in all scenarios. The potential for the metabolites NOA409045, CGA67868 and SYN546520 to leach to ground water has been assessed using the same approach.

The maximum PEC_{GW} of NOA409045 was ~~6.666~~ 9.163 µg/L ~~and 8.397 µg/L for both CZ uses and SZ uses respectively,~~ however an assessment concluding the non-relevance of NOA409045 in groundwater is presented in the Part B Section 10 of this submission. The assessment of metabolite NOA409045 is crucial for the authorisation process. Therefore further refinement and toxicological data are required. For the conclusions of the evaluation please refer to Part B Section 10.

The maximum PEC_{GW} of CGA67868 was ~~0.194~~ 0.267 µg/L ~~and 0.252 µg/L for both CZ uses and SZ uses respectively,~~ however an assessment concluding the non-relevance of CGA67868 in groundwater is presented in the Part B Section 10 of this submission.

The maximum PEC_{GW} of SYN546520 were either ~~14.494~~ 14.671 µg/L (Tier 1) and ~~3.222~~ 3.248 µg/L (Tier 2) ~~or 19.099 µg/L (Tier 1) and 4.149 µg/L (Tier 2) for CZ uses and SZ uses respectively,~~ however an assessment concluding the non-relevance of SYN546520 in groundwater is presented in the Part B Section 10 of this submission.

~~Based on the assessment~~ If the groundwater metabolite NOA409045 will be consider as not relevant in Section B10, the use of metalaxyl-M, ~~is not expected to lead to leaching into groundwater at levels that would be unacceptable when~~ applied according to the recommended use pattern, will be acceptable.

Oxathiapiprolin

Groundwater modelling on oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 has not been previously reviewed at an EU level, and is provided in support of this assessment in Part B Section 8, Appendix 3.

The Predicted Environmental Concentration of oxathiapiprolin and soil metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 in ground water (PEC_{GW}) has been assessed with the standard FOCUS scenarios, the FOCUS PEARL v5.5.5., FOCUS PELMO v6.6.4 and MACRO v5.5.4 models, and using endpoints established in the EU review (EFSA Journal 2016; 14(7):4504) ~~for CZ uses and endpoints calculated based on the recommendations in the latest guideline (EF SA, 2014) for SZ uses. The individual values from which the endpoints were calculated are those established in the EU review.~~

The PEC_{GW} of oxathiapiprolin at 1m depth following 20 years use on leafy vegetables at 2 × 15 g a.s./ha from growth state of BBCH 12 and 25% foliar interception, was less than 0.1 µg/L in all scenarios. The

potential for the metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 to leach to ground water has been assessed using the same approach.

The PEC_{GW} of IN-RDT31 was less than 0.1 $\mu\text{g/L}$ in all scenarios.

The PEC_{GW} of IN-RAB06 was less than 0.1 $\mu\text{g/L}$ in all scenarios.

The PEC_{GW} of IN-QPS10 was less than 0.1 $\mu\text{g/L}$ in all scenarios.

The maximum PEC_{GW} of IN-E8S72 was 1.929 1.931 $\mu\text{g/L}$ and 1.939 1.941 $\mu\text{g/L}$ for CZ-uses and SZ-uses respectively, however an assessment concluding the non-relevance of IN-E8S72 in groundwater is presented in the Part B Section 10 of this submission.

Based on the assessment, the use of oxathiapiprolin is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

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

The FOCUS Step 2 PEC_{sw} values for NEU and SEU were considered in the evaluation for CEU. This approach had no impact on the conclusions of the evaluation.

Zonal (field) uses

Metalaxyl-M

Surface water modelling on metalaxyl-M and its metabolite NOA409045 has not been previously reviewed at an EU level, and is provided in support of this assessment in Part B Section 8, Appendix 3.

PEC_{sw} and PEC_{sed} for metalaxyl-M

The Predicted Environmental Concentration of metalaxyl-M in surface water and sediment (PEC_{sw} and PEC_{sed}) have been assessed with the FOCUS SW STEPS 1-2 v3.2 model and endpoints established in the EU review (EFSA Journal 2015; 13(3):3999).

Based on the recommended uses on bulb vegetables or leafy vegetables at $2 \times 87.2 \text{ g a.s./ha}$ and application at BBCH 12, the maximum PEC_{sw} values for metalaxyl-M were 6.01 $\mu\text{g/L}$ and 10.79 $\mu\text{g/L}$ (Step 2) in NEU and SEU respectively. The maximum PEC_{sed} values for metalaxyl-M were 2.36 $\mu\text{g/kg}$ and 4.24 $\mu\text{g/kg}$ (Step 2) in NEU and SEU respectively. These simulations are described further in the Part B Section 8

PEC_{sw} and PEC_{sed} for NOA409045

The Predicted Environmental Concentration of metabolite NOA409045 in surface water and sediment (PEC_{sw} and PEC_{sed}) have been assessed with the FOCUS SW STEPS 1-2 v3.2 model and endpoints established in the EU review (EFSA Journal 2015; 13(3):3999).

Based on the recommended uses on bulb vegetables or leafy vegetables at $2 \times 87.2 \text{ g a.s./ha}$ and application at BBCH 12, the maximum PEC_{sw} values for NOA409045 were 11.27 $\mu\text{g/L}$ and 21.36 $\mu\text{g/L}$ (Step 2) in NEU and SEU respectively. The maximum PEC_{sed} values for NOA409045 were 1.36 $\mu\text{g/kg}$ and 2.58 $\mu\text{g/kg}$ (Step 2) in NEU and SEU respectively. These simulations are described further in the Part B Section 8.

Oxathiapiprolin

Surface water modelling on oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41, and IN-P3X26 has not been previously reviewed at an EU level, and is provided in support of this assessment in Part B Section 8, Appendix 3.

PEC_{sw} and PEC_{sed} for oxathiapiprolin

The Predicted Environmental Concentration of oxathiapiprolin in surface water and sediment (PEC_{sw} and

PEC_{SED}) have been assessed with the FOCUS SW STEPS 1-2 v3.2 model and endpoints established in the EU review (EFSA Journal 2016; 14(7):4504).

Based on the recommended uses on bulb vegetables or leafy vegetables at 2×15 g a.s./ha and application at BBCH 12, the maximum PEC_{SW} values for oxathiapiprolin were 0.22 µg/L and 0.41 µg/L (Step 2) in NEU and SEU respectively. The maximum PEC_{SED} values for oxathiapiprolin were 14.37 µg/kg and 27.10 µg/kg (Step 2) in NEU and SEU respectively. These simulations are described further in the Part B Section 8

PEC_{SW} and PEC_{SED} for IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41, and IN-P3X26

The Predicted Environmental Concentration of metabolites IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41, and IN-P3X26 in surface water and sediment (PEC_{SW} and PEC_{SED}) have been assessed with the FOCUS SW 1-2 v3.2 model and endpoints established in the EU review (EFSA Journal 2016; 14(7):4504).

Based on the recommended uses on bulb vegetables or leafy vegetables at 2×15 g a.s./ha and application at BBCH 12, the maximum PEC_{SW} values for IN-RDT31 were 0.07 µg/L and 0.13 µg/L (Step 2) in NEU and SEU respectively. The maximum PEC_{SED} values were 0.77 µg/kg and 1.54 µg/kg (Step 2) in NEU and SEU respectively.

The maximum PEC_{SW} values for IN-RAB06 were 0.26 µg/L and 0.51 µg/L (Step 2) in NEU and SEU respectively. The maximum PEC_{SED} values for IN-RAB06 were 1.29 µg/kg and 2.51 µg/kg (Step 2) in NEU and SEU respectively.

The maximum PEC_{SW} values for IN-QPS10 were 0.01 µg/L and 0.03 µg/L (Step 2) in NEU and SEU respectively. The maximum PEC_{SED} values for IN-QPS10 were 0.65 µg/kg and 1.31 µg/kg (Step 2) in NEU and SEU respectively.

The maximum PEC_{SW} values for IN-E8S72 were 0.06 µg/L and 0.12 µg/L (Step 2) in NEU and SEU respectively. The maximum PEC_{SED} values for IN-E8S72 were < 0.01 µg/kg and 0.01 µg/kg (Step 2) in NEU and SEU respectively.

The maximum PEC_{SW} values for IN-S2K66 were 0.17 µg/L and 0.31 µg/L (Step 2) in NEU and SEU respectively. The maximum PEC_{SED} values for IN-S2K66 were 1.17 µg/kg and 2.19 µg/kg (Step 2) in NEU and SEU respectively.

The maximum PEC_{SW} values for IN-RSE01 were 0.20 µg/L and 0.38 µg/L (Step 2) in NEU and SEU respectively. The maximum PEC_{SED} values for IN-RSE01 were 1.43 µg/kg and 2.69 µg/kg (Step 2) in NEU and SEU respectively.

The maximum PEC_{SW} values for IN-RYJ52 were 0.31 µg/L and 0.59 µg/L (Step 2) in NEU and SEU respectively. The maximum PEC_{SED} values for IN-RYJ52 were 2.21 µg/kg and 4.16 µg/kg (Step 2) in NEU and SEU respectively.

The maximum PEC_{SW} values for IN-Q7D41 were 0.23 µg/L and 0.43 µg/L (Step 2) in NEU and SEU respectively. The maximum PEC_{SED} values for IN-Q7D41 were 1.61 µg/kg and 3.03 µg/kg (Step 2) in NEU and SEU respectively.

The maximum PEC_{SW} values for IN-P3X26 were 0.21 µg/L and 0.39 µg/L (Step 2) in NEU and SEU respectively. The maximum PEC_{SED} values for IN-P3X26 were 1.43 µg/kg and 2.69 µg/kg (Step 2) in NEU and SEU respectively.

These simulations are described further in the Part B Section 8.

PEC_{SW} for A23109A on bulb vegetables or leafy vegetables

The PEC_{SW} of A23109A has been assessed with the Rautmann percentage drift data. Based on the recommended use rate of 0.5 L p.p.p./ha (537 g p.p.p./ha), the maximum initial Predicted Environmental Concentration in surface water (PEC_{SW}) of A23109A will be 4.958 µg/L.

The results for PEC_{SW} and PEC_{SED} modelling are used in the Ecotox risk assessment, as detailed in Part B Section 9 of this submission.

Interzonal (protected) uses

Metalaxyl-M

Surface water modelling on metalaxyl-M and its metabolite NOA409045 has not been previously reviewed at an EU level, and is provided in support of this assessment in Part B Section 8, Appendix 3.

PEC_{SW} and PEC_{SED} for metalaxyl-M

The Predicted Environmental Concentration of metalaxyl-M in surface water and sediment (PEC_{SW} and PEC_{SED}) have been assessed with the FOCUS SW STEPS 1-2 v3.2 model and endpoints established in the EU review (EFSA Journal 2015; 13(3):3999) for CZ uses and endpoints calculated based on the recommendations in the latest guideline (EFSA, 2014) for SZ uses.

Based on the recommended uses on leafy vegetables at 2×87.2 g a.s./ha and application at BBCH 12, the maximum PEC_{SW} values for metalaxyl-M were either 5.21 µg/L and 9.19 µg/L (Step 2) in NEU and SEU respectively for CZ uses, or 5.60 µg/L and 9.98 µg/L (Step 2) in NEU and SEU respectively for SZ uses. The maximum PEC_{SED} values for metalaxyl-M were either 2.05 µg/kg and 3.62 µg/kg (Step 2) in NEU and SEU respectively for CZ uses, or 2.78 µg/kg and 4.96 µg/kg (Step 2) in NEU and SEU respectively for SZ uses. These simulations are described further in the Part B Section 8

PEC_{SW} and PEC_{SED} for NOA409045

The Predicted Environmental Concentration of metabolite NOA409045 in surface water and sediment (PEC_{SW} and PEC_{SED}) have been assessed with the FOCUS SW STEPS 1-2 v3.2 model and endpoints established in the EU review (EFSA Journal 2015; 13(3):3999) for CZ uses and endpoints calculated based on the recommendations in the latest guideline (EFSA, 2014) for SZ uses.

Based on the recommended uses on leafy vegetables at 2×87.2 g a.s./ha and application at BBCH 12, the maximum PEC_{SW} values for NOA409045 were either 9.58 µg/L and 18.00 µg/L (Step 2) in NEU and SEU respectively for CZ uses, or 9.96 µg/L and 18.76 µg/L (Step 2) in NEU and SEU respectively for SZ uses. The maximum PEC_{SED} values for NOA409045 were either 1.16 µg/kg and 2.18 µg/kg (Step 2) in NEU and SEU respectively for CZ uses, or 1.34 µg/kg and 2.52 µg/kg (Step 2) in NEU and SEU respectively for SZ uses. These simulations are described further in the Part B Section 8.

Oxathiapiprolin

Surface water modelling on oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41, and IN-P3X26 has not been previously reviewed at an EU level, and is provided in support of this assessment in Part B Section 8, Appendix 3.

PEC_{SW} and PEC_{SED} for oxathiapiprolin

The Predicted Environmental Concentration of oxathiapiprolin in surface water and sediment (PEC_{SW} and PEC_{SED}) have been assessed with the FOCUS SW STEPS 1-2 v3.2 model and endpoints established in the EU review (EFSA Journal 2016; 14(7):4504) for CZ uses and endpoints calculated based on the recommendations in the latest guideline (EFSA, 2014) for SZ uses.

Based on the recommended uses on leafy vegetables at 2×15 g a.s./ha and application at BBCH 12, the maximum PEC_{SW} values for oxathiapiprolin were either 0.19 µg/L and 0.34 µg/L (Step 2) in NEU and SEU respectively for CZ uses, or 0.19 µg/L and 0.35 µg/L (Step 2) in NEU and SEU respectively for SZ

uses. The maximum PEC_{SED} values for oxathiapiprolin were 12.25 µg/kg and 22.86 µg/kg (Step 2) in NEU and SEU respectively for both CZ and SZ uses. These simulations are described further in the Part B Section 8.

PEC_{SW} and PEC_{SED} for IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41, and IN-P3X26

The Predicted Environmental Concentration of metabolites IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 in surface water and sediment (PEC_{SW} and PEC_{SED}) have been assessed with the FOCUS SW 1-2 v3.2 model and endpoints established in the EU review (EFSA Journal 2016; 14(7):4504) for CZ uses and endpoints calculated based on the recommendations in the latest guideline (EFSA, 2014) for SZ uses.

Based on the recommended uses on leafy vegetables at 2 × 15 g a.s./ha and application at BBCH 12, the maximum PEC_{SW} values for IN-RDT31 were either 0.05 µg/L and 0.11 µg/L (Step 2) in NEU and SEU respectively for CZ uses, or 0.06 µg/L and 0.12 µg/L (Step 2) in NEU and SEU respectively for SZ uses. The maximum PEC_{SED} values were either 0.64 µg/kg and 1.28 µg/kg (Step 2) in NEU and SEU respectively for CZ uses, or 0.61 µg/kg and 1.21 µg/kg (Step 2) in NEU and SEU respectively for SZ uses.

The maximum PEC_{SW} values for IN-RAB06 were 0.22 µg/L and 0.43 µg/L (Step 2) in NEU and SEU respectively for both CZ and SZ uses. The maximum PEC_{SED} values for IN-RAB06 were either 1.09 µg/kg and 2.10 µg/kg (Step 2) in NEU and SEU respectively for CZ uses, or 1.08 µg/kg and 2.08 µg/kg (Step 2) in NEU and SEU respectively for SZ uses.

The maximum PEC_{SW} values for IN-QPS10 were either 0.01 µg/L and 0.02 µg/L (Step 2) in NEU and SEU respectively for CZ uses, or 0.01 µg/L and 0.03 µg/L (Step 2) in NEU and SEU respectively for SZ uses. The maximum PEC_{SED} values for IN-QPS10 were either 0.54 µg/kg and 1.09 µg/kg (Step 2) in NEU and SEU respectively for CZ uses, or 0.52 µg/kg and 1.03 µg/kg (Step 2) in NEU and SEU respectively for SZ uses.

The maximum PEC_{SW} values for IN-E8S72 were 0.05 µg/L and 0.10 µg/L (Step 2) in NEU and SEU respectively for both CZ and SZ uses. The maximum PEC_{SED} values for IN-E8S72 were < 0.01 µg/kg and 0.01 µg/kg (Step 2) in NEU and SEU respectively for both CZ and SZ uses.

The maximum PEC_{SW} values for IN-S2K66 were 0.14 µg/L and 0.26 µg/L (Step 2) in NEU and SEU respectively for both CZ and SZ uses. The maximum PEC_{SED} values for IN-S2K66 were 1.00 µg/kg and 1.85 µg/kg (Step 2) in NEU and SEU respectively for both CZ and SZ uses.

The maximum PEC_{SW} values for IN-RSE01 were 0.17 µg/L and 0.32 µg/L (Step 2) in NEU and SEU respectively for both CZ and SZ uses. The maximum PEC_{SED} values for IN-RSE01 were 1.22 µg/kg and 2.27 µg/kg (Step 2) in NEU and SEU respectively for both CZ and SZ uses.

The maximum PEC_{SW} values for IN-RYJ52 were 0.27 µg/L and 0.50 µg/L (Step 2) in NEU and SEU respectively for both CZ and SZ uses. The maximum PEC_{SED} values for IN-RYJ52 were 1.89 µg/kg and 3.51 µg/kg (Step 2) in NEU and SEU respectively for both CZ and SZ uses.

The maximum PEC_{SW} values for IN-Q7D41 were 0.20 µg/L and 0.36 µg/L (Step 2) in NEU and SEU respectively for both CZ and SZ uses. The maximum PEC_{SED} values for IN-Q7D41 were 1.38 µg/kg and 2.55 µg/kg (Step 2) in NEU and SEU respectively for both CZ and SZ uses.

The maximum PEC_{SW} values for IN-P3X26 were 0.18 µg/L and 0.33 µg/L (Step 2) in NEU and SEU respectively for both CZ and SZ uses. The maximum PEC_{SED} values for IN-P3X26 were 1.22 µg/kg and 2.27 µg/kg (Step 2) in NEU and SEU respectively for both CZ and SZ uses.

These simulations are described further in the Part B Section 8.

PEC_{SW} for A23109A on leafy vegetables

The PEC_{SW} of A23109A has been assessed with the Rautmann percentage drift data. Based on the recommended use rate of 0.5 L p.p.p./ha (537 g p.p.p./ha), the maximum initial Predicted Environmental Concentration in surface water (PEC_{SW}) of A23109A will be 4.958 µg/L.

The results for PEC_{SW} and PEC_{SED} modelling are used in the Ecotox risk assessment, as detailed in Part B Section 9 of this submission.

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

Metalaxyl-M

The fate and behaviour in air of metalaxyl-M was evaluated during EU review (EFSA Journal 2015; 13(3):3999). No additional studies have been performed.

The vapour pressure at 25°C of the active substance metalaxyl-M is $> 10^{-5}$ Pa. Hence metalaxyl-M is regarded as volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by metalaxyl-M due to volatilization with subsequent deposition should be considered. Nonetheless, as mitigation measures to reduce exposure to non-target or aquatic organisms (FOCUS Surface Water Step 4) were not required, and due to the short DT₅₀ (< 2 days), the exposure by volatilisation is considered negligible compared to other routes (spray drift and drainage). Thus, PEC air is deemed not required for metalaxyl-M.

Oxathiapiprolin

The fate and behaviour in air of oxathiapiprolin was evaluated during EU review (EFSA Journal 2016; 14(7):4504). No additional studies have been performed.

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

3.8 Ecotoxicology (Part B, Section 9)

Additional active substance data submitted by the applicant were considered by zRMS/izRMS as not necessary for authorisation. Therefore, according to SANCO/10328/2004 – rev 9 (21.10.2021) point 4.2.1, those studies were not evaluated by zRMS/izRMS.

The metalaxyl-M is the avian risk driver in the formulation (95.4% of the toxicity). Therefore, the acute oral toxicity study conducted with A23109A is not required. Therefore, the study No. VV-891190 (2021), was not evaluated by zRMS/izRMS.

3.8.1 Effects on terrestrial vertebrates

Zonal (field) uses

The acute and long-term risks of A23109A to birds and mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with A23109A, metalaxyl-M and oxathiapiprolin, and maximum residues occurring on food items following applications according to the proposed use pattern.

As requested in the Working document on Risk Assessment of Plant Protection Products in the Central Zone – Ecotoxicology (May 2021), a calculation of long-term combitox risk according to the concentration addition (CA) model was provided.

Risk of secondary poisoning has also been assessed, as oxathiapiprolin and some of its metabolites have log P_{ow} values of > 3.0 . The risk to birds and mammals from exposure *via* drinking water has also been assessed.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk (including secondary poisoning and combined reproductive toxicity), indicating

that the risk to birds and mammals is acceptable following use of A23109A according to the proposed use pattern.

Interzonal (protected) uses

The acute and long-term risks of A23109A to birds and mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with A23109A, metalaxyl-M and oxathiapiprolin, and maximum residues occurring on food items following applications according to the proposed use pattern.

As requested in the Working document on Risk Assessment of Plant Protection Products in the Central Zone – Ecotoxicology (May 2021), a calculation of long-term combitox risk according to the concentration addition (CA) model was provided.

Risk of secondary poisoning has also been assessed, as oxathiapiprolin and some of its metabolites have log P_{ow} values of > 3.0 . The risk to birds and mammals from exposure *via* drinking water has also been assessed.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk (including secondary poisoning and combined reproductive toxicity), indicating that the risk to birds and mammals is acceptable following use of A23109A according to the proposed use pattern.

3.8.2 Effects on aquatic species

Zonal (field) uses

The PEC/RAC ratios, using worst-case Step 1 or Step 2 PEC_{SW} values for metalaxyl-M, oxathiapiprolin and their metabolites are less than the trigger value of 1, for all aquatic organisms.

The PEC/RAC ratios, using worst-case PEC_{SW} values for A23109A, are also less than the trigger value of 1, for all aquatic organisms.

The toxic unit analysis indicated that neither metalaxyl-M nor oxathiapiprolin was driving the toxicity of the mixture therefore a quantitative mixture toxicity risk assessment was conducted. The RQ_{mix} values for all organism groups are below the trigger value of 1 when worst case Step 1 or Step 2 PEC_{SW} values are considered.

Acceptable risks to aquatic organisms following the proposed uses of A23109A have therefore been demonstrated without the need for any application mitigation.

Interzonal (protected) uses

The PEC/RAC ratios, using worst-case Step 1 or Step 2 PEC_{SW} values for metalaxyl-M, oxathiapiprolin and their metabolites are less than the trigger value of 1, for all aquatic organisms.

The PEC/RAC ratios, using worst-case PEC_{SW} values for A23109A, are also less than the trigger value of 1, for all aquatic organisms.

The toxic unit analysis indicated that neither metalaxyl-M nor oxathiapiprolin was driving the toxicity of the mixture therefore a quantitative mixture toxicity risk assessment was conducted. The RQ_{mix} values for all organism groups are below the trigger value of 1 when worst case Step 1 or Step 2 PEC_{SW} values are considered.

Acceptable risks to aquatic organisms following the proposed use of A23109A have therefore been demonstrated without the need for any application mitigation.

3.8.3 Effects on bees

Zonal (field) uses

The risk to honeybees was assessed following SANCO/10329/2002 rev.2 and EPPO, 2010 as proposed in the list of guidance documents relevant to the implementation of Regulation 1107/2009, published in the

official EU Journal 2013/C 95/01 and 95/02.

The risk of A23109A to honeybees was assessed from hazard quotients, estimated from acute oral and contact studies with metalaxyl-M, oxathiapiprolin and A23109A. The acute oral and contact hazard quotients were less than the relevant trigger of 50, indicating that the risk to honeybees is acceptable following use of A23109A according to the proposed use pattern.

In addition, the acute risk to honeybees was assessed from hazard quotients (HQ) and Exposure Toxicity Ratios (ETRs) following EFSA Bee Guidance Document (2013) using endpoints from acute oral and contact studies with metalaxyl M and oxathiapiprolin. Acute contact HQ and oral ETR values were less than the relevant triggers at the screening step, indicating acceptable acute risk to adult honeybees.

The chronic adult and larval risk of A23109A to honeybees was assessed from ETRs following EFSA Bee Guidance Document (2013) using endpoints from chronic adult oral and larval studies with metalaxyl M and oxathiapiprolin. At the screening step assessment the ETR values for chronic adult oral and larval toxicity were below the relevant trigger values for oxathiapiprolin, as was the larval ETR for metalaxyl M, thereby demonstrating acceptable risks to honeybees following the proposed uses of A23109A.

A Tier 1 chronic adult oral risk assessment for metalaxyl M in the treated crop was conducted. The ETR values for all proposed uses were below the relevant trigger values thereby demonstrating an acceptable chronic risk to adult honeybees following the proposed uses of A23109A.

The screening step assessment for the combined effects of metalaxyl M and oxathiapiprolin indicated an acceptable risk to honeybees for acute oral and contact exposure and larval exposure but a Tier I risk assessment was necessary for chronic adult oral exposure. However, an assessment of the contribution of each active substance to the mixture toxicity showed that metalaxyl M was driving the toxicity (>90%) therefore the Tier I chronic adult oral risk assessment for the mixture is covered by the Tier I risk assessment for metalaxyl M which demonstrated acceptable risks to honeybees following the proposed uses of A23109A.

Interzonal (protected) uses

The risk to honeybees was assessed following SANCO/10329/2002 rev.2 and EPPO, 2010 as proposed in the list of guidance documents relevant to the implementation of Regulation 1107/2009, published in the official EU Journal 2013/C 95/01 and 95/02.

The risk of A23109A to honeybees was assessed from hazard quotients, estimated from acute oral and contact studies with metalaxyl-M, oxathiapiprolin and A23109A. The acute oral and contact hazard quotients were less than the relevant trigger of 50, indicating that the risk to honeybees is acceptable following use of A23109A according to the proposed use pattern.

In addition, the acute risk to honeybees was assessed from hazard quotients (HQ) and Exposure Toxicity Ratios (ETRs) following EFSA Bee Guidance Document (2013) using endpoints from acute oral and contact studies with metalaxyl M and oxathiapiprolin. Acute contact HQ and oral ETR values were less than the relevant triggers at the screening step, indicating acceptable acute risk to adult honeybees.

The chronic adult and larval risk of A23109A to honeybees was assessed from ETRs following EFSA Bee Guidance Document (2013) using endpoints from chronic adult oral and larval studies with metalaxyl M and oxathiapiprolin. At the screening step assessment the ETR values for chronic adult oral and larval toxicity were below the relevant trigger values for oxathiapiprolin, as was the larval ETR for metalaxyl M, thereby demonstrating acceptable risks to honeybees following the proposed uses of A23109A.

A Tier 1 chronic adult oral risk assessment for metalaxyl M in the treated crop was conducted. The ETR values for all proposed uses were below the relevant trigger values thereby demonstrating an acceptable

chronic risk to adult honeybees following the proposed uses of A23109A.

The screening step assessment for the combined effects of metalaxyl-M and oxathiapiprolin indicated an acceptable risk to honeybees for acute oral and contact exposure and larval exposure but a Tier I risk assessment was necessary for chronic adult oral exposure. However, an assessment of the contribution of each active substance to the mixture toxicity showed that metalaxyl-M was driving the toxicity (>90%) therefore the Tier I chronic adult oral risk assessment for the mixture is covered by the Tier I risk assessment for metalaxyl-M which demonstrated acceptable risks to honeybees following the proposed uses of A23109A.

The data requirements in accordance with Commission Regulation (EU) No 284/2013 for the chronic toxicity to adult honeybees and honeybee larvae are fulfilled.

3.8.4 Effects on other arthropod species other than bees

Zonal (field) uses

At Tier 1, the in-field HQ values based on the LR₅₀ were greater than the trigger value for the worst-case intended use scenarios. However, extended laboratory test data for four species, including *Typhlodromus pyri* and *Aphidius rhopalosiphi*, confirmed that the in-field risks following the proposed uses of A23109A were acceptable.

At Tier 1, the off-field HQ values based on the LR₅₀ were below the trigger value for the worst-case intended use scenarios thereby demonstrating that the off-field risks following the proposed uses of A23109A were acceptable.

Interzonal (protected) uses

At Tier 1, the in-field HQ values based on the LR₅₀ were greater than the trigger value for the worst-case intended use scenarios. However, extended laboratory test data for four species, including *Typhlodromus pyri* and *Aphidius rhopalosiphi*, confirmed that the in-field risks following the proposed uses of A23109A were acceptable.

At Tier 1, the off-field HQ values based on the LR₅₀ were below the trigger value for the worst-case intended use scenarios thereby demonstrating that the off-field risks following the proposed uses of A23109A were acceptable.

3.8.5 Effects on soil organisms

Zonal (field) uses

Soil meso- and macrofauna

The risk of A23109A to earthworms was assessed from acute and long-term toxicity exposure ratios (TERs) between the selected toxicity endpoints for A23109A, metalaxyl-M, oxathiapiprolin and their relevant metabolites, and the maximum PEC_{soil}. The acute and long-term TER values derived are greater than the Regulation (EU) 546/2011 triggers of 10 and 5, respectively, indicating that the risk to earthworms is acceptable following use of A23109A according to the proposed use pattern.

The risk of A23109A to other non-target soil macro-organisms, as represented by *Folsomia* and *Hypoaspis* was assessed from long-term toxicity exposure ratios (TERs) between the selected no-effect concentrations or EC₁₀ values, derived from laboratory tests on A23109A, metalaxyl-M, oxathiapiprolin and their relevant metabolites, and the maximum PEC_{soil}. The long-term TER values are all greater than the recommended trigger value of 5, indicating that the risk to soil macro-organisms is acceptable following use of A23109A according to the proposed use pattern.

Soil micro-organisms

The risk of A23109A, metalaxyl-M, oxathiapiprolin and their relevant metabolites to soil micro-organisms was evaluated by comparison of the maximum concentrations with effects <25% derived from laboratory tests, with the maximum PEC_{soil}.

All the effect levels exceeded the relevant PEC_{soil} values, indicating that the risk to soil micro-organisms is acceptable following the use of A23109A according to the proposed use pattern.

Interzonal (protected) uses

Soil meso- and macrofauna

The risk of A23109A to earthworms was assessed from acute and long-term toxicity exposure ratios (TERs) between the selected toxicity endpoints for A23109A, metalaxyl-M, oxathiapiprolin and their relevant metabolites, and the maximum PEC_{soil} . The acute and long-term TER values derived are greater than the Regulation (EU) 546/2011 triggers of 10 and 5, respectively, indicating that the risk to earthworms is acceptable following use of A23109A according to the proposed use pattern.

The risk of A23109A to other non-target soil macro-organisms, as represented by *Folsomia* and *Hypoaspis* was assessed from long-term toxicity exposure ratios (TERs) between the selected no-effect concentrations or EC_{10} values, derived from laboratory tests on A23109A, metalaxyl-M, oxathiapiprolin and their relevant metabolites, and the maximum PEC_{soil} . The long-term TER values are all greater than the recommended trigger value of 5, indicating that the risk to soil macro-organisms is acceptable following use of A23109A according to the proposed use pattern.

Soil micro-organisms

The risk of A23109A, metalaxyl-M, oxathiapiprolin and their relevant metabolites to soil micro-organisms was evaluated by comparison of the maximum concentrations with effects <25% derived from laboratory tests, with the maximum PEC_{soil} .

All the effect levels exceeded the relevant PEC_{soil} values, indicating that the risk to soil micro-organisms is acceptable following the use of A23109A according to the proposed use pattern.

3.8.6 Effects on non-target terrestrial plants

Zonal (field) uses

Screening test rates up to and including 1000 mL/ha were tested for six plant species with formulation A23109A. Less than 50% effect on seedling emergence and vegetative vigour on all six species was observed at the maximum test rate of 1000 mL A23109A/ha. This indicates that the risk to non-target terrestrial plants in off-crop areas is acceptable following use of A23109A according to the proposed use pattern.

Interzonal (protected) uses

Screening test rates up to and including 1 000 mL/ha were tested for six plant species with formulation A23109A. Less than 50% effect on seedling emergence and vegetative vigour on all six species was observed at the maximum test rate of 1 000 mL A23109A/ha. This indicates that the risk to non-target terrestrial plants in off-crop areas is acceptable following use of A23109A according to the proposed use pattern.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Tests on other non-target species are not required.

3.9 Relevance of metabolites (Part B, Section 10)

Zonal (field) uses

Metalaxyl-M

The metalaxyl-M metabolites NOA409045, SYN546520 and CGA67868 are predicted to occur in groundwater at concentrations above 0.1 µg/L (see A23109A Part B Section 8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

NOA409045

The relevance of the groundwater metabolite NOA409045 was already assessed at EU level (Review Report, SANTE/11112/2019).

Considering all available studies, the groundwater metabolite NOA409045 is considered not relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

A summary of the relevance assessment for NOA409045 is given in the table below:

Table 3.9-1: Summary of the relevance assessment for NOA409045 (field)

Table 3.9-1. Summary of the relevance assessment for NOA409045 (HED)				
	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC _{GW}	6.666 9.163 µg/L
			Based on	Modelling result using FOCUS PEARL v5.5.5 / Cabbage 2 x 87.2 g a.s./ha One application in each of two crop cycles, BBCH 12, Hamburg scenario (Chapter 8.8.2, Part B Section 8)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolites CGA62826 and NOA409045	Non-genotoxic, confirmed in <i>in vivo</i> micronucleus assays with both CGA62826 and NOA409045
		Stage 3	Toxic properties of metabolite (CGA62826)	Acute oral tox >2000 mg/kg Acute dermal tox >2000 mg/kg 28 day (gavage): NOAEL = 1000 mg/kg/day
			Classification of parent	H302 H318
			Classification of metabolite	Less toxic than the parent compound. No classification for reproductive toxicity or carcinogenic properties
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Not acceptable (>0.75 µg/L)
	STEP 5	Refined risk assessment		Acceptable
		Predicted exposure (% of ADI infant)		0.27%
			ADI based on	0.5 mg/kg bw/day (28 day sub-chronic (oral), NOAEL = 1000 mg/kg bw/day)

It is concluded that the levels of exposure of NOA409045 which have the potential to exceed 0.75 µg/L in groundwater at 1m depth, are far below the established ADI and do not present a risk to human health.

SYN546520

The relevance of the metalaxyl-M groundwater metabolite SYN546520 has already been assessed and the assessment agreed at EU level (see **EFSA Journal 2015; 13(3):3999**).

SYN546520 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in the table below.

Table 3.9-2: Summary of the relevance assessment for SYN546520 (field)

Table 3.1-2: Summary of the relevance assessment for STN-46526 (Red)				
	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC _{GW}	Tier 1: 15.462 µg/L Tier 2: 3.489 µg/L
			Based on	Modelling result using FOCUS PEARL v5.5.5 / Onions 2 x 87.2 g a.s./ha, BBCH 12, Hamburg scenario. (Chapter 8.8.2, Part B Section 8)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite (CGA108906)	Non-genotoxic
		Stage 3	Toxic properties of metabolite (CGA108906)	Acute oral tox >2000 mg/kg Acute dermal tox >2000 mg/kg 28 day (gavage): NOAEL = 200 mg/kg/day
			Classification of parent	H302 H318
			Classification of metabolite	No classification for reproductive toxicity or carcinogenic properties
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Not acceptable (>0.75 µg/L)
	STEP 5	Refined risk assessment		Acceptable
		Predicted exposure (% of ADI infant)		2.3%, Tier 1 0.5%, Tier 2
				#ADI based on

- 100 fold inter & intraspecies safety factor & additional 10 fold safety factor for extrapolation to chronic exposure & additional 2 fold safety factor for SYN546520 content in the test material

It is concluded that the levels of exposure of SYN546520 which have the potential to exceed 0.75 µg/L in groundwater at 1m depth, are far below the established ADI and do not present a risk to human health.

CGA67868

The relevance of the metalaxyl-M groundwater metabolite CGA67868 has already been assessed and the assessment agreed at EU level (see **EFSA Journal 2015; 13(3):3999**).

CGA67868 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in the table below:

Table 3.9-3: Summary of the relevance assessment for CGA67868 (field)

		Assessment step		Result of assessment	
		STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC _{GW}	0.194 0.267 µg/L	
			Based on	Modelling result using FOCUS PEARL v5.5.5 / Cabbage 2 x 87.2 g a.s./ha BBCH 12, One applications in each of two crop cycles Second crop cycle, BBCH 12, Hamburg scenario (Chapter 8.8.2, Part B Section 8)	
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No	
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic	
		Stage 3	Toxic properties of metabolite	NA	
			Classification of parent	H302 H318	
			Classification of metabolite	No classification for reproductive toxicity or carcinogenic properties	
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable (<0.75µg/L)	
	STEP 5		Refined risk assessment	NA	
			Predicted exposure (% of ADI)	NA	
				ADI based on	NA

NA: not applicable

It is concluded that the levels of exposure of CGA67868 do not have the potential to exceed 0.75 µg/L in groundwater at 1m depth, and do not present a risk to human health.

Oxathiapiprolin

IN-E8S72

The metabolite IN-E8S72 is predicted to occur in groundwater at concentrations >0.75µg/L but <10µg/L. (see Chapter 8.8 of the dRR Part B, Section 8). Only assessment of the relevance of metabolite IN-E8S72 according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore required.

The relevance of the groundwater metabolite IN-E8S72 has already been assessed and the assessment agreed at EU level (**EFSA Journal 2016;14(7):4504**), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{GW} calculated for the GAP and groundwater scenarios considered in this dRR). IN-E8S72 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 – rev.10. A summary of the relevance assessment is given in the table below.

Table 3.9-4: Summary of the relevance assessment for IN-E8S72 (field)

Table 8.7-11: Summary of the relevance assessment for IN-E8S72 (H4d)				
	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	2.238 µg/L
			Based on	Modelling result using FOCUS PEARL v5.5.5 / Onions 2 x 15 g a.s./ha BBCH 12, Châteaudun scenario. (Chapter 8.8.2, Part B Section 8)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	None
			Classification of parent	None
			Classification of metabolite	None
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Not acceptable (>0.75 µg/L)
	STEP 5		Refined risk assessment	Acceptable
			Predicted exposure (% of ADI infant)	<0.1 %
				ADI based on

It is concluded that the levels of exposure of IN-E8S72 which have the potential to exceed 0.75 µg/L in groundwater at 1m depth, are far below the established ADI and do not present a risk to human health.

Interzonal (protected) uses

Metalaxyl-M

The metalaxyl-M metabolites NOA409045, SYN546520 and CGA67868 are predicted to occur in groundwater at concentrations above 0.1 µg/L (see A23109A Part B Section 8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

NOA409045

The relevance of the groundwater metabolite NOA409045 was already assessed at EU level (Review Report, SANTE/11112/2019).

Considering all available studies, the groundwater metabolite NOA409045 is considered not relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10.

A summary of the relevance assessment for NOA409045 is given in the table below:

Table 3.9-5: Summary of the relevance assessment for NOA409045 (protected)

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Groundwater	STEP 2		Max PEC _{GW}	6.080 9.163 µg/L

			Based on	Modelling result using FOCUS PELMO v6.6.4 / Cabbages 2 x 87.2 g a.s./ha. Two applications in one crop cycle, BBCH 12, Hamburg scenario. (Chapter 8.8.2, Part B Section 8)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolites CGA62826 and NOA409045	Non-genotoxic, confirmed in <i>in vivo</i> micronucleus assays with both CGA62826 and NOA409045
		Stage 3	Toxic properties of metabolite (CGA62826)	Acute oral tox >2000 mg/kg Acute dermal tox >2000 mg/kg 28 day (gavage): NOAEL = 1000 mg/kg/day
			Classification of parent	H302 H318
			Classification of metabolite	Less toxic than the parent compound. No classification for reproductive toxicity or carcinogenic properties
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Not acceptable (>0.75 µg/L)
	STEP 5		Refined risk assessment	Acceptable
			Predicted exposure (% of ADI infant)	0.27%
				ADI based on

SYN546520

The relevance of the metalaxyl-M groundwater metabolite SYN546520 has already been assessed and the assessment agreed at EU level (see **EFSA Journal 2015; 13(3):3999**).

SYN546520 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in the table below.

Table 3.9-6: Summary of the relevance assessment for SYN546520 (protected)

Summary of the relevance assessment for BTHS 16216 (protected)				
	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of ground water contamination	STEP 2		Max PEC _{GW}	Tier 1: 19.099 µg/L Tier 2: 4.149 µg/L
			Based on	Modelling result using FOCUS PEARL v5.5.5 / Cabbage 2 x 87.2 g a.s./ha. Two applications in one crop cycle, BBCH 12, Jokioinen scenario in SEU. (Chapter 8.8.2, Part B Section 8)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite (CGA108906)	Non-genotoxic
		Stage 3	Toxic properties of metabolite (CGA108906)	Acute oral tox >2000 mg/kg Acute dermal tox >2000 mg/kg 28 day (gavage): NOAEL = 200 mg/kg/day
			Classification of parent	H302 H318
			Classification of metabolite	No classification for reproductive toxicity or carcinogenic properties
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Not acceptable (>0.75 µg/L)
	STEP 5		Refined risk assessment	Acceptable
			Predicted exposure (% of ADI infant)	2.9%, Tier 1 0.6%, Tier 2
				#ADI based on

- 100 fold inter & intraspecies safety factor & additional 10 fold safety factor for extrapolation to chronic exposure & additional 2 fold safety factor for SYN546520 content in the test material

CGA67868

The relevance of the metalaxyl-M groundwater metabolite CGA67868 has already been assessed and the assessment agreed at EU level (see **EFSA Journal 2015; 13(3):3999**).

CGA67868 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is given in the table below:

Table 3.9-7: Summary of the relevance assessment for CGA67868 (protected)

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC _{GW}	0.194 0.267 µg/L
			Based on	Modelling result using FOCUS PEARL v5.5.5 / Cabbage 2 x 87.2 g a.s./ha BBCH 12, One applications in each of two crop cycles, BBCH 12, Hamburg scenario in CEU. (Chapter 8.8.2, Part B Section 8)

Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite	NA
			Classification of parent	H302 H318
			Classification of metabolite	No classification for reproductive toxicity or carcinogenic properties
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Acceptable (<0.75µg/L)
	STEP 5		Refined risk assessment	NA
			Predicted exposure (% of ADI)	NA
			ADI based on	NA

NA: not applicable

Oxathiapiprolin

IN-E8S72

The metabolite IN-E8S72 is predicted to occur in groundwater at concentrations >0.75µg/L but <10µg/L. (see Chapter 8.8 of the dRR Part B, Section 8). Only assessment of the relevance of metabolite IN-E8S72 according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore required.

The relevance of the groundwater metabolite IN-E8S72 has already been assessed and the assessment agreed at EU level (**EFSA Journal 2016;14(7):4504**), and the relevance assessment is applicable as well for the GAP and groundwater scenarios considered in this dRR (i.e., the conclusions reached at Step 4 and 5 of the relevance assessment made at the EU-level are valid also with regard to the PEC_{GW} calculated for the GAP and groundwater scenarios considered in this dRR). IN-E8S72 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 – rev.10. A summary of the relevance assessment is given in the table below.

Table 3.9-8: Summary of the relevance assessment for IN-E8S72 (protected)

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC _{gw}	1.939 1.941 µg/L
			Based on	Modelling result using FOCUS PEARL v5.5.5 / Cabbage 2 x 15 g a.s./ha. One application in each of two crop cycles, BBCH 12, Hamburg scenario in SEU. (Chapter 8.8.2, Part B Section 8)
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite	Non-genotoxic
		Stage 3	Toxic properties of metabolite;	None
			Classification of parent	None
			Classification of metabolite	None

Consumer health risk assessment	STEP 4	Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Not acceptable (>0.75 µg/L)
	STEP 5	Refined risk assessment	Acceptable
		Predicted exposure (% of ADI infant)	<0.1 %
		ADI based on	The ADI for IN-E8S72 was derived from the 28-day toxicity studies in the rat study and using a safety factor of 1000. The ADI for IN-E8S72 is 1.157 mg/kg bw/day.

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

Orondis VIP (A23109A) contains the active substances metalaxyl-M and oxathiapiprolin which are not approved as candidates for substitution. Therefore a comparative assessment is not required.

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

Efficacy:

The following claimed uses have not been accepted to be registered on the ground of article 33 of regulation 1107/2009 (:

1. Leek (ALLPO): *Phytophthora porri* (PHYTPO)

Justification: not supported by efficacy trials from the NE EPPO climatic zone

National registration requirements: min. 6 efficacy trials/ 2 seasons (including 2-3 efficacy trials from the NE zone because of this use is new for the mixture of metalaxyl-M and oxathiapiprolin in Poland)

2. Head cabbage (BRSOL): *Hyaloperonospora parasitica* (PEROPA)

Justification: insufficient number of efficacy trials (3 efficacy trials from the NE zone and 1 efficacy trial from Germany)

National registration requirements: min. 6 efficacy trials/ 2 seasons (this use is new for the mixture of metalaxyl-M and oxathiapiprolin in Poland)

There is possible registration on the grounds of article 51 of regulation 1107/2009 (without efficacy trials) for the following uses:

- Leek (ALLPO)
- Head cabbage (BRSOL)

Additional remarks:

1. National registration requirements are based on the updated harmonization arrangements, updated extrapolation table (update of 15.09.2023), including additional note regarding required trials for extrapolated crops: "The higher number of trials required refers to plant protection products containing a new active substance, a new mixture of previously unused active substances, a new use".

2. For these uses for which extrapolation is not possible:

- the requirement to submit a minimum of 6 efficacy trials in major crops and 2-3 efficacy trials for known uses or 4 trials for new uses in minor crops,
- trials from 2 crop seasons are required, while it is possible to reduce the number of seasons to 1 - only if the expert accepts the substantive argumentation of such a decision presented by the applicant, supported by more than the required minimum number of trials.

3. Location of required trials: North-East EPPO zone (including Poland) or countries neighbouring Poland (Czech Republic, Germany, Slovakia). In case of new uses/new active substance/new mixture of

known active substances, submission of efficacy trials from the NE zone (in addition to trials from neighbouring countries) is obligatory. Minimum 2-3 efficacy trials from the NE zone should be presented.

~~Analytical methods:~~

~~Impurity 2 [(2,6 dimethyl phenyl) (2 methoxyacetyl) amino] propionic acid 1-methoxycarbonyl ethyl ester (coded CGA226048) was considered as non relevant at the time of submission, due to ongoing discussions on EU level (EFSA). In case this impurity is considered as relevant, the availability of a validated method is considered as a data requirement. However as the discussion on the impurities on EU level is still ongoing the analytical method for impurity should be available. According to the information provided by the applicant on the zRMS request, the relevant analytical method for CGA226048 is under development.~~

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Komentarz oceniających:

Etykieta została sprawdzona w zakresie fizykochemii, metod analitycznych, toksykologii i istotności toksykologicznej metabolitów, pozostałości, losu i zachowania, ekotoksykologii oraz skuteczności. Zmiany wynikające z oceny wprowadzono do poniższej etykiety w widoczny sposób, poprzez zaznaczenie ich szarym podświetleniem tekstu (fragmenty dodane) lub przekreśleniem i jasno-szarym cieniem (fragmenty usunięte).

Zakres zmian jest następujący:

Sekcja właściwości fizykochemiczne:

1. Środek nie wykazuje właściwości wybuchowych i utleniających, znakowanie środka wynikające z wyżej wymienionych właściwości fizykochemicznych zgodne z zapisami Rozporządzenia Parlamentu Europejskiego i Rady (WE) NR 1272/2008 z dnia 16 grudnia 2008 r. nie jest wymagane.
2. Okres ważności: 2 lata na podstawie zaakceptowanych 2-letnich badań stabilności środka ochrony roślin przechowywanego w opakowaniach wykonanych z HDPE. Trwają 3-letnie badania stabilności. Można uznać warunkowo 3-letni okres przechowywania środka ochrony roślin w opakowaniach wykonanych z HDPE na podstawie zaakceptowanego 4-tygodniowego badania przyspieszonego starzenia w temperaturze 54°C. W związku z powyższym, wszystkie opakowania wymienione, w punktach 2.1 dokumentu A i 4.1 Sekcji 1,2,4 można uznać za odpowiednie do celów transportu i magazynowania środka ochrony roślin.
3. Brak uwag do punktów dotyczących warunków przechowywania i bezpiecznego usuwania środka ochrony roślin i opakowania oraz sporządzania cieczy użytkowej.
4. Brak uwag do zapisu nazw grup chemicznych, do których przyporządkowano substancje czynne i ich zawartości (gęstość względna zgodnie z punktem 2.6.1 Sekcji 1,2,4 wynosi 1,074).
5. Zgodnie z informacjami zawartymi w punktach IIIA 2.9.1 i IIIA 2.9.2 Sekcji 1,2,4 Raportu Rejestracyjnego środek nie jest dedykowany do łącznego stosowania.

Sekcja skuteczność:

1. Zgodnie ze zmianą klasyfikacji podstawy z art. 51 na art. 33 w przypadku sałaty i mączniaka rzekomego w zastosowaniu gruntowym i w szklarni, w etykiecie wprowadzono stosowne zmiany.
2. Z uwagi na to, że tabela GAP nie uwzględnia zastosowania środka w produkcji szkółkarskiej, zalecenia to zostało wykreślone w strategii antyodpornościowej.
3. Dodano procedurę mycia opryskiwacza.

Sekcja metody analityczne:

1. Brak uwag.

Sekcja toksykologia i istotność toksykologiczna metabolitów:

1. W części dotyczącej klasyfikacji zagrożeń wprowadzono zmiany oznakowania zgodnie z wynikami badań *in vivo*. W podsekcji „Zapobieganie” dodano zwroty P261 oraz P280,
2. W podsekcji „Reagowanie” dodano zwrot P302 + P352; Zwroty P333+P313 oraz P337+P313 przeniesiono do części etykiety „Pierwsza Pomoc”, usunięty zwrot P264 z części „Pierwsza Pomoc” został pozostawiony w części „Reagowanie”,
3. W części dotyczącej „Środków ostrożności dla osób stosujących środek” zapis zmodyfikowano zgodnie z ustaleniami harmonizacyjnymi dotyczącymi stosowania PPE (Toks. Min Rol. stan na 26.10.2021).
4. W części dotyczącej „Stosowanie środka” dodano informację dotyczącą ograniczania znosu cieczy roboczej podczas wykonywania zabiegu agrochemicznego przez zastosowanie (drift reduction technology (DRT) „Dysze z 50% redukcję znosu”.
5. W części dotyczącej „Środków ostrożności dla osób stosujących środek” dodano zapis dotyczący wyznaczenia strefy buforowej dookoła szklarni zgodnie z ustaleniami harmonizacyjnymi dotyczącymi stosowania PPE (Toks. Min Rol. stan na 25.09.2023).

Sekcja pozostałości:

1. Następujące uprawy zostały wykreślone z etykiety ze względu na możliwość przekroczeń wartości NDP dla substancji metalaxyl-M i/lub oksatiapiprolin: jarmuż, rośliny kapustne uprawiane na liście, kapusta pekińska, szczypiorek, rukiew wodna, rośliny zielarskie, pietruszka naciowa.
2. Ze względu na to, że z całej grupy roślin zielarskich jedynie zastosowanie środka w ochronie bazyli i kwiatów jadalnych nie przekracza wartości NDP, grupa roślin zielarskich została wykreślona z etykiety, a zastosowanie na bazylię zostało dopisane (zasotowanie w ochronie roślin uprawianych na kwiaty jadalne było już wcześniej uwzględnione w etykiecie).

3. Wprowadzono zapis do etykiety dotyczący roślin następczych: „Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.”
4. W trakcie etapu komentowania Niemcy zaproponowali zmianę okresu karencji dla upraw, który byłby zgodny z proponowanymi klasami dotyczącymi okresów karencji opublikowanymi w SANCO 7039/VI/95 z 22.07.1997, na co Wnioskodawca wyraził zgodę. Okresy karencji dla upraw wynoszące 20 dni zmieniono na 21 dni.

Sekcja los i zachowanie w środowisku:

1. Nie wprowadzono zmian w etykiecie.

Sekcja ekotoksykologia:

1. Usunięto zapis „Unikać niezgodnego z przeznaczeniem uwalniania do środowiska”.
2. Dodano zwrot 501.

Załącznik do zezwolenia MRiRW nr: R-...../2022 z dnia06.2022 r.

Posiadacz zezwolenia:

Syngenta Polska Sp. z o.o., ul. Szamocka 8, 01-748 Warszawa.

Tel.: 22 326-06-01 (www.syngenta.pl).

Podmiot odpowiedzialny za końcowe etykietowanie i pakowanie środka ochrony roślin:

ORONDIS VIP



Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

metalaksyl-M (substancja z grupy fenyloamidów) – 174,4 g/l (16.24%),

oksatiapiprolin (związek z grupy piperydynylo-tiazolo-izoksazolin) – 30 g/l (2,79%).

Zezwolenie MRiRW nr: R-...../2022 z dnia06.2022 r.

 	
GHS07 GHS09	
Uwaga	
H317	Może powodować reakcję alergiczną skóry.
H319	Działa drażniąco na oczy.
H411	Działa toksycznie na organizmy wodne, powodując długotrwałe zmiany.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P261	Unikać wdychania mgły/par
P280	Stosować rękawice ochronne/ochronę oczu/ochronę twarzy
P264	Dokładnie umyć ręce po użyciu
P362+P364	Zdjąć zanieczyszczoną odzież i wyprać przed ponownym użyciem.
P333+P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: zasięgnąć porady /zgłosić się pod opiekę lekarza.
P305+P351+P338	W przypadku dostania się do oczu: ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P302 + P352	W PRZYPADKU DOSTANIA SIĘ NA SKÓRĘ: Umyć dużą ilością wody lub...
P337+P313	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać do...

OPIS DZIAŁANIA

FUNGICYD, koncentrat dyspergujący do stosowania po rozcieńczaniu wodą (DC), o działaniu powierzchniowym, wgłębnym i układowym, do stosowania zapobiegawczego w okresie intensywnego wzrostu roślin w zwalczaniu chorób powodowanych przez grzyby.

Środek zawiera substancję czynną metalaksyl-M należącą wg FRAC do grupy 4 i oksatiapiprolin – wg FRAC grupa 49.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych oraz opryskiwaczy ręcznych i plecakowych. **Dysze z 50% redukcją znosu (drift reduction technology) (DRT).**

Kapusta głowiasta (uprawa w polu)

~~Head-cabbage (field)~~

mączniak rzekomy kapustnych (Hyaloperonospora parasitica)

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

Termin stosowania: środek stosować od fazy widocznego 2. liścia do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-49).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7–10 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp między zabiegami: 7-10 dni.

Zalecana ilość wody: 200–800 l/ha.

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

Cebula (uprawa w polu)

~~Onion (field)~~

mączniak rzekomy cebuli (Peronospora destructor)

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

Termin stosowania: środek stosować od fazy widocznego 2. liścia do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-48).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym /na tym samym polu: 2.

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody: 200–800 l/ha.

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

Por (uprawa w polu)

~~Leek (field)~~

fytoftorosa pora (Phytophthora porri)

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

Termin stosowania: środek stosować od fazy widocznego 2. liścia do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-48).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 12-14 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym /na tym samym polu: 2.

Odstęp między zabiegami: 12-14 dni.

Zalecana ilość wody: 200–800 l/ha.

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

Salata (uprawa w polu lub w szklarniach)

mączniak rzekomy (Bremia lactucae /Peronospora sp.)

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

Termin stosowania:

- środek stosować od fazy widocznego 2. liścia właściwego do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-49),

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym /na tym samym polu: 2.

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody: 200-800 l/ha

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

STOSOWANIE ŚRODKA OCHRONY ROŚLIN W UPRAWACH I ZASTOSOWANIACH MAŁOBSZAROWYCH

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

Brokuł, kalafior, brukselka, ~~jarmuż, rośliny kapustne uprawiane na liście~~, gorczyca (uprawa w polu)

~~Broccoli, cauliflower, Brussel sprouts, curly kale, leafy brassica, mustard (field)~~

mączniak rzekomy kapustnych (Hyaloperonospora parasitica), bielik krzyżowych (biała rdza krzyżowych) (Albugo candida)

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

Termin stosowania: środek stosować od fazy widocznego 2. liścia do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-49).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7–10 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.
Odstęp między zabiegami: 7-10 dni.
Zalecana ilość wody: 200–800 l/ha.
Ilość wody dostosować do wielkości roślin i ich zagęszczenia.
Zalecane opryskiwanie: drobnokropliste.

Kapusta głowiasta (uprawa w polu)

~~Head cabbage (field)~~

bielik krzyżowych (biała rdza krzyżowych) (Albugo candida)

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

Termin stosowania: środek stosować od fazy widocznego 2. liścia do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-49).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7–10 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp między zabiegami: 7-10 dni.

Zalecana ilość wody: 200–800 l/ha.

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

Kapusta włoska, ~~kapusta pekińska~~ (uprawa w polu)

~~Savoy cabbage, Pe-tsai (field)~~

mączniak rzekomy kapustnych (Hyaloperonospora parasitica)

bielik krzyżowych (biała rdza krzyżowych) (Albugo candida)

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

Termin stosowania: środek stosować od fazy widocznego 2. liścia do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-49).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7–10 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2.

Odstęp między zabiegami: 7-10 dni.

Zalecana ilość wody: 200–800 l/ha.

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

Cebula (uprawa w polu)

~~Onion (field)~~

fytoftorozę pora (Phytophthora porri)

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

Termin stosowania: środek stosować od fazy widocznego 2. liścia do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-48).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym /na tym samym polu: 2.

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody: 200–800 l/ha.

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

Szalotka, cebula na zielony szczypior, cebula siedmiolatka, czosnek (uprawa w polu)

~~Shallot, spring/ green/ Welsh onion, garlic (field)~~

fytoftorozę pora (Phytophthora porri), *mączniak rzekomy cebuli (Peronospora destructor)*

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

Termin stosowania: środek stosować od fazy widocznego 2. liścia do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-48).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7 dniach dla szalotki, czosnku i szczypioru lub 12-14 dniach dla cebuli siedmiolatki i na zielony szczypior, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym /na tym samym polu: 2.

Odstęp między zabiegami: co najmniej 7 dni (szalotka, czosnek) lub 12-14 dni (cebula siedmiolatka lub na zielony szczypior).

Zalecana ilość wody: 200–800 l/ha.

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

Por (uprawa w polu)

~~Leek (field)~~

mączniak rzekomy cebuli (Peronospora destructor)

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

Termin stosowania: środek stosować od fazy widocznego 2. liścia do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-48).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 12-14 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym /na tym samym polu: 2.

Odstęp między zabiegami: 12-14 dni.

Zalecana ilość wody: 200–800 l/ha.

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

~~Salata, Endywia, szpinak, burak liściowy (boćwina)/burak uprawiany na liście, cykoria салатowa, portulaka warzywna, roszponka warzywna, rukola (rokietta siewna), szczypiorek, rzeżucha ogrodowa (pieprzycza siewna), rukiew wodna, rośliny zielarskie, bazylia, rośliny uprawiane na kwiaty jadalne, rośliny warzywne uprawiane na młode liście (uprawa w polu)~~

~~Lettuce, endive/escarole, spinach, chard/beet leaves, chicory, purslane, lamb's lettuce, rocket, chives, cress, watercress, herbs, edible flowers, baby leaf crops (field)~~

mączniak rzekomy (Bremia lactucae /Peronospora sp.), fytoftoroz pora na szczypioru (Phytophthora porri)

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

Termin stosowania:

- środek stosować od fazy widocznego 2. liścia właściwego do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-49),
- dla roślin warzywnych uprawianych na młode liście – od fazy widocznego 2. do 8. liścia właściwego (BBCH 12-18).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym /na tym samym polu: 2.

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody:

- ~~salata~~, rośliny warzywne uprawiane na młode liście, cykoria салатowa, roszponka warzywna, rukola, ~~szczypiorek~~, rzeżucha ogrodowa, ~~rukiew wodna~~, endywia, ~~rośliny zielarskie~~, **bazylia**, rośliny uprawiane na kwiaty jadalne – 200–800 l/ha,
- szpinak, burak liściowy (boćwina)/burak uprawiany na liście, portulaka – 200–600 l/ha.

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

~~Salata, Endywia, cykoria салатowa, roszponka warzywna, rukola (rokietta siewna), rzeżucha ogrodowa (pieprzycza siewna), rukiew wodna, rośliny warzywne uprawiane na młode liście (uprawa w szklarniach)~~

~~Lettuce, endive/escarole, chicory, lamb's lettuce, rocket, cress, watercress, baby leaf crops (greenhouses)~~

mączniak rzekomy (Bremia lactucae /Peronospora sp.)

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

Termin stosowania:

- środek stosować od fazy widocznego 2. liścia właściwego do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-49),
- dla roślin warzywnych uprawianych na młode liście – od fazy widocznego 2. do 8. liścia właściwego (BBCH 12-18).

Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7 dniach, zależnie od presji chorób.

Maksymalna liczba zabiegów w sezonie wegetacyjnym /na tym samym polu: 2.

Odstęp między zabiegami: co najmniej 7 dni.

Zalecana ilość wody:

- ~~sałata~~, rośliny warzywne uprawiane na młode liście, cykoria sałatowa, roszponka warzywna, rukola, rzeżucha ogrodowa, ~~rukiew wodna~~, endywia, ~~rośliny zielarskie~~, rośliny uprawiane na kwiaty jadalne **młode liście** – 200–800 l/ha,
- ~~szpinak, burak liściowy (boćwina)/burak uprawiany na liście, portulaka~~ – 200–600 l/ha.

Ilość wody dostosować do wielkości roślin i ich zagęszczenia.

Zalecane opryskiwanie: drobnokropliste.

~~Pietruszka naciowa (uprawa w polu)~~

~~Parsley (field)~~

~~*mączniak rzekomy (Plasmopara umbelliferarum/Peronospora nivea)*~~

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

~~Termin stosowania: środek stosować od fazy widocznego 2. liścia właściwego do końca fazy wzrostu i rozwoju części roślin przeznaczonych do zbioru (BBCH 12-49).~~

~~Pierwszy zabieg wykonać zapobiegawczo, przed pojawieniem się pierwszych objawów chorób, następny w miarę potrzeby po 7 dniach, zależnie od presji chorób.~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym /na tym samym polu: 2.~~

~~Odstęp między zabiegami: co najmniej 7 dni.~~

~~Zalecana ilość wody: 200–800 l/ha.~~

~~Ilość wody dostosować do wielkości roślin i ich zagęszczenia.~~

~~Zalecane opryskiwanie: drobnokropliste.~~

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

- sałata, endywia, szpinak, burak liściowy (boćwina)/burak uprawiany na liście, cykoria sałatowa, portulaka warzywna, roszponka warzywna, rukola (rakieta siewna), rzeżucha ogrodowa (pieprzycza siewna), ~~rukiew wodna, rośliny zielarskie~~, **bazylia**, rośliny uprawiane na kwiaty jadalne, rośliny warzywne uprawiane na młode liście, ~~pietruszka naciowa, szczypiórek~~ – 10 dni,
- cebula, szalotka, cebula na zielony szczypior, cebula siedmiolatka, czosnek, por – 14 dni,
- brokuł, kalafior, brukselka, ~~jarmuż~~, kapusta głowiasta, kapusta włoska, ~~kapusta pekińska, rośliny kapustne uprawiane na liście~~, gorczyca – 20 **21** dni.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następnie: nie ma ograniczeń co do okresu od ostatniego zastosowania środka do dnia, w którym można siać lub sadzić rośliny uprawiane następnie.

1. Warunkiem skuteczności zabiegu jest dokładne pokrycie roślin cieczą użytkową.
2. Podczas stosowania środka nie dopuścić do:
 - znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
 - nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
3. Środek Orondis VIP zawiera substancję czynną metalaksyl-M (wg FRAC grupa 4) oraz oksatiapiprolin (wg FRAC grupa 49). Wielokrotne stosowanie środka lub innych środków

zawierających substancje czynne o takim samym mechanizmie działania może doprowadzić do zmniejszenia skuteczności działania środka.

W ramach strategii przeciwdziałania odporności poszczególnych sprawców chorób zaleca się m. in.:

1. stosowanie środka wyłącznie zapobiegawczo oraz zgodnie z zaleceniami podanymi w etykiecie,
2. stosowanie środka maksymalnie w odstępach 14-dniowych lub krótszych w przypadku wysokiej presji chorób,
3. stosowanie środka naprzemiennie z fungicydami o potwierdzonej skuteczności w zwalczaniu danej choroby z innych grup chemicznych, celem uniknięcia odporności krzyżowej (środki spoza grupy 4 i 49 wg FRAC),
4. stosowanie środka Orondis VIP lub innego produktu zawierającego substancję z grupy 49 wg FRAC nie więcej, niż w 1/3 przyjętego programu ochrony danej uprawy, z uwzględnieniem maksymalnej liczby 2. aplikacji środkiem Orondis VIP,
5. stosowanie nie więcej, niż 4. aplikacji środkami zawierającymi oksatiapiprolin lub substancje z grupy FRAC 49 na danej uprawie, a w przypadku ilości zabiegów fungicydowych mniejszej, niż 3. aplikacje – środek Orondis VIP lub inny produkt z grupy FRAC 49 stosować 1 raz w sezonie,
6. nie stosować środka Orondis VIP lub innego produktu zawierającego substancję z grupy 4. wg FRAC częściej, niż 2-krotnie z rzędu,
7. w przypadku upraw następczych – nie stosować więcej, niż 6 zabiegów na rok środkami zawierającymi oksatiapiprolin lub inne substancje z grupy 49 wg klasyfikacji FRAC na tym samym obszarze dla tego samego patogenu (sprawcy danej choroby),
- ~~8. nie stosować środka Orondis VIP, ani jakiegokolwiek innego produktu zawierającego oksatiapiprolin w produkcji szkółkarskiej lub w produkcji sadzonek~~
9. nie stosować środka Orondis VIP lub innych środków zawierających substancje z grupy 49 wg klasyfikacji FRAC w zabiegach nalistnych, jeśli środki te zastosowano wcześniej do zaprawiania nasion użytych w produkcji danej uprawy lub dogłębowo przeciwko tym samym patogenom.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

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 mieszałem).

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 mieszało hydrauliczne, ciecz mechanicznie wymieszać.

W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

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

Po pracy aparaturę dokładnie wymyć. W tym celu trzeba całkowicie opróżnić system i przepłukać czystą wodą zbiornik opryskiwacza, belkę i dyszę dwa do trzech razy, aż do usunięcia piany i wszelkich śladów preparatu.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

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

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

~~Stosować rękawice, okulary i maseczkę ochronną oraz odzież roboczą w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.~~

Stosować rękawice ochronne, ochronę oczu i twarzy oraz odzież roboczą (kombinezon), w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu

W celu ochrony osób postronnych oraz mieszkańców konieczne jest wyznaczenie strefy buforowej dookoła obiektów - szklarnie:

„W czasie oprysku należy zastosować co najmniej 10 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.”.

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

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

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

~~Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.~~

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o następującej szerokości od zbiorników i cieków wodnych:

- uprawy w polu – 1 metr,
- uprawy w szklarniach – nie dotyczy.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHEWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C - 30°C,

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.

~~P264 – Dokładnie umyć ręce po użyciu.~~

P333+P313 – W przypadku wystąpienia podrażnienia skóry lub wysypki: zasięgnąć porady /zgłosić się pod opiekę lekarza.

~~P362+P364 – Zdjąć zanieczyszczoną odzież i wyprać przed ponownym użyciem.~~

~~P305+P351+P338 – W przypadku dostania się do oczu: ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.~~

P337+P313 – W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

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

Okres ważności - 2 3 lata.

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

The letter of access from Corteva Agriscience International Sàrl (formally DuPont International Operations Sàrl; change effective January 4, 2021) (hereafter called “Corteva”) is submitted with this dossier.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP Section 2	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Chemical Characterization Before Storage of Batch JHU003-044-001 Final Report Report No. SMG16480 Document No. VV-903866 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.1	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physical and Technical Properties of Batch JHU003-044-001 Report No. SMG16481 Document No. VV-903873 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.2	Jackson, W.	13/11/2020	Oxathiapiprolin/Metalaxyl-M A23109A - Safety Study Final Report Report No. HT20/577 Document No. VV-903887 Test Facility Syngenta Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 2.3	Jackson, W.	13/11/2020	Oxathiapiprolin/Metalaxyl-M A23109A - Safety Study Final Report Report No. HT20/577 Document No. VV-903887 Test Facility Syngenta Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.4	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physico-Chemical Characteristics of Batch JHU003-044-001 Final Report Report No. SMG16482 Document No. VV-903874 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.4	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physical and Technical Properties of Batch JHU003-044-001 Report No. SMG16481 Document No. VV-903873 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.5	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physico-Chemical Characteristics of Batch JHU003-044-001 Final Report Report No. SMG16482 Document No. VV-903874 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 2.6	Breedt, C.	25/05/2021	Oxathiapiprolin/Metalaxyl-M A23109A - Storage Stability and Shelf Life Statement (2 Weeks and 4 Weeks 54 °C) in Packaging Made of HDPE According to CIPAC MT 46.4 Report No. 300185324 Document No. VV-903892 Test Facility Syngenta Crop Protection AG, GLP Testing Facility WMU Not GLP Unpublished	N	N	N/A	SYN	N/A
KCP 2.7	Breedt, C.	25/05/2021	Oxathiapiprolin/Metalaxyl-M A23109A - Storage Stability and Shelf Life Statement (2 Weeks and 4 Weeks 54 °C) in Packaging Made of HDPE According to CIPAC MT 46.4 Report No. 300185324 Document No. VV-903892 Test Facility Syngenta Crop Protection AG, GLP Testing Facility WMU Not GLP Unpublished	N	N	N/A	SYN	N/A
KCP 2.7	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physico-Chemical Characteristics of Batch JHU003-044-001 Final Report Report No. SMG16482 Document No. VV-903874 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 2.7	Breedt, C.	10/02/2023	Oxathiapiprolin/Metalaxyl-M A23109A - Storage Stability and Shelf Life Statement (2 years 25 °C) in Packaging Made of HDPE Final Report Report No. 300224746 Document No. VV-982143 Test Facility Syngenta Crop Protection AG, GLP Testing Facility WMU Not GLP Unpublished	N	N	N/A	SYN	N/A
KCP 2.8.2	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physical and Technical Properties of Batch JHU003-044-001 Report No. SMG16481 Document No. VV-903873 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.8.3	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physical and Technical Properties of Batch JHU003-044-001 Report No. SMG16481 Document No. VV-903873 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.8.3	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physico-Chemical Characteristics of Batch JHU003-044-001 Final Report Report No. SMG16482 Document No. VV-903874 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 2.8.5.1	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physical and Technical Properties of Batch JHU003-044-001 Report No. SMG16481 Document No. VV-903873 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.8.5.1	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physico-Chemical Characteristics of Batch JHU003-044-001 Final Report Report No. SMG16482 Document No. VV-903874 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.11	Breedt, C.	17/12/2020	A23109A – The Effectiveness of the Spray Tank Cleaning Procedure Report No. 450796 Document No. VV-903870 Test Facility Syngenta Crop Protection AG, GLP Testing Facility WMU Not GLP Unpublished	N	N	N/A	SYN	N/A
KCP 2.11	Breedt, C.	19/04/2021	A23109A Procedure for Cleaning Application Equipment Report No. N/A Document No. VV-903868 Test Facility N/A Not GLP Unpublished	N	N	N/A	SYN	N/A

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 2.11	Breedt, C.	19/04/2021	A23109A: Procedures for Destruction or Decontamination of the Plant Protection Product and its Packaging Report No. N/A Document No. VV-903869 Test Facility N/A Not GLP Unpublished	N	N	N/A	SYN	N/A
KCP 2.11	Jackson, W.	13/11/2020	Oxathiapiprolin/Metalaxyl-M A23109A - Oxidation/Reduction: Chemical Incompatibility Final Report Report No. HT20/578 Document No. VV-903889 Test Facility Syngenta Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.11	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Chemical Characterization Before Storage of Batch JHU003-044-001 Final Report Report No. SMG16480 Document No. VV-903866 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.1/01	Bradbury, L.	20/04/2021	SF-1027/2- Determination of Metalaxyl-M (achiral and chiral) and Oxathiapiprolin in A23109A by HPLC Report No. N/A Document No. VV-903867 Test Facility N/A Not GLP Unpublished	N	N	N/A	SYN	N/A

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 5.1.1/02	Heintz, K.	11/12/2014	A9651D - Analytical Method SD-1751/1 Report No. 300021240 Document No. VV-128413 , A9651D_10487 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	N/A	SYN	N/A
KCP 5.1.1/03	Heintz, K.	25/11/2014	A9651D - Validation Analytical Method SD-1751/1 Report No. CHMU140410 Document No. VV-411110 , A9651D_10488 Test Facility Syngenta Crop Protection GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCP 5.1.1/04	Heintz, K.	08/07/2021	Statement on Validation of the Analytical Method SD-1751/1 for the Determination of CGA72649 and CGA363736 in A23109A Oxathiapiprolin/metalaxyl-M DC (030/180) Report No. N/A Document No. VV-910672 Test Facility Syngenta Crop Protection AG, GLP Testing Facility WMU Not GLP Unpublished	N	N	N/A	SYN	N/A
KCP 5.1.1/05	Khot, S.	05/04/2021	A23109A – Validation of Analytical Method SF-1027/2 Report No. SMG16622 Document No. VV-903871 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.1/06	Heintz, K.	28/11/2023	Statement on Validation of the Analytical Method SD-1751/1 for the determination of CGA72649 and CGA363736 in A23109A oxathiapiprolin/metalaxyl-M DC (030/180) Report No. N/A Syngenta Crop Protection AG Not GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 5.1.1/07	Stephanie Sigel/Sandro Tamburello	11/07/2024	Analytical Method SD-2790/1– Metalaxyl-M, SD-2790/1– Determination of CGA226048 in technical material and formulations by LC/MS Analytical Method. Syngenta Crop Protection AG. Report No. not available Document No. VV-1043801 Not GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.1/08	Stephanie Sigel	02/07/2024	Metalaxyl-M - A9642D - Validation of Analytical Method SD-2790/1, Final Report. Syngenta Crop Protection AG. Report No. CHMU240179 Document No. VV-1043800 GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.1/09	Stephanie Sigel	11/07/2024	Statement on Validation of the Analytical Method SD-2790/1 for the determination of CGA226048 in A23109A oxathiapiprolin/metalaxyl-M DC (030/180). Syngenta Crop Protection AG. Report No. not available Document No. VV-1043799 Not GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	Donald, C. Gibson, R.	27/08/2020	Oxathiapiprolin (SYN546539): Validation of the Analytical Method DuPont-30422 for the Determination of Residues of Oxathiapiprolin in Crop Matrices by LC-MS/MS Report No. 231693 Document No. VV-870136 Test Facility Charles River Laboratories Edinburgh, Ltd. GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	Y Please refer to Data point column
KCP 5.1.2	Eckert, J.	14/01/2016	Metalaxyl-M SL (A13947A) – Honey Bee (Apis mellifera L.) Larval Toxicity Test (Repeated Exposure) Report No. S15-02457 Document No. VV-415529 , A13947A_11455 Test Facility Eurofins Agroscience Services GmbH GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y KCP 10.3.1.3

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	Previously used Y/N If yes, for which data point?
KCP 5.1.2	Ford, K.	15/12/2020	Oxathiapiprolin – Honey Residue Study on Spring Oilseed Rape in Northern and Southern Europe in 2020 Report No. CEMR-9533 Document No. VV-885771 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	Y Please refer to Data point column
KCP 5.2.1	Fritzsche S, Mohaupt R	2022	Metalaxyl-M – Extraction Efficiency Study on Leaf Lettuce, Grapes, Pepper Corn and Dried Hops in the Germany and Italy in 2021 Report No S21-03444. Syngenta File No. VV-951401 GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	Hillier, K.	05/05/2021	Metalaxyl-M - Validation of Analytical Method REM181.13A for the Determination of Residues of Metalaxyl-M in Crop and Processed Matrices by LC-MS/MS Report No. GS12ND Document No. VV-901824 Test Facility Covance Laboratories Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	xxxxxxxxx	17/08/2012	Metalaxyl-M – Validation of Analytical Method GRM031.06A for the Determination of Residues of Metalaxyl-M and Structurally Related Metabolites as the Common Moiety 2,6-Dimethylaniline (CGA72649) in Animal Matrices Report No. S11-03382 Document No. VV-402332 , CGA329351_11524 Test Facility xxxxxxxxxxxxxxxxxxxxxxxx GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	Lunsmann, V.	07/12/2020	Oxathiapiprolin - Analytical Method ECO_052_03A and Validation for the Determination of Oxathiapiprolin in Honey Bee Larvae Diets and Adult Honey Bee Feeding Solutions Report No. 20 35 CRB 0103 Document No. VV-884296 Test Facility BioChem agrar GmbH GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	Y Please refer to Data point column

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	Previously used Y/N If yes, for which data point?
KCP 5.1.2	Lünsmann, V.	20/10/2021	Metalaxyl-M – Analytical Method ECO_048_03A and Validation for the Determination of Metalaxyl-M in Honey Bee Larvae Diets, Adult Honey Bee Feeding Solutions and Bumble Bee Contact Test Solutions Report No.:21 35 CRB 0059, Document No.: VV-928043 Test Facility BioChem Agrar, Germany GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	Oberrauch, S.	2017	Oxathiapiprolin (DPX-QGU42) technical: Honey bee (Apis mellifera L.) 22 day larval toxicity test (repeated exposure) Report Number S17-01639 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH, Eutinger Str. 24, 75223 Niefern-Öschelbronn, Germany GLP Unpublished DAS Study No. DuPont-48606	N/A	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	Corteva (SYN LoA)	N/R, Please refer to data owner
KCP 5.1.2	Reinhardt, R. Lakaschus, S.	27/04/2020	Oxathiapiprolin - Residue Study on Protected Lettuce in Northern France, Germany, Italy, Spain and the United Kingdom in 2019 Report No. S19-02718 Document No. VV-854039 Test Facility Eurofins Agrosience Services Chem GmbH GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	Y Please refer to Data point column
KCP 5.1.2	xxxxxxxxxx	26/02/2021	Oxathiapiprolin/Metalaxyl-M DC (A23109A) - Toxicity to the Rainbow Trout Oncorhynchus mykiss under Laboratory Conditions (Acute Toxicity Test – Static) Report No. S20-06894 Document No. VV-893371 Test Facility xxxxxxxxxxxx GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 5.1.2	Schuler, L.	12/04/2021	Oxathiapiprolin/Metalaxyl-M DC (A23109A) - Toxicity to the Single Cell Green Alga Raphidocelis subcapitata Korshikov under Laboratory Conditions Report No. S20-06896 Document No. VV-898484 Test Facility Eurofins Agroscience Services EcoTox GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	Schuler, L.	26/02/2021	Oxathiapiprolin/metalaxyl-M DC (A23109A) - Toxicity to the Water Flea Daphnia magna Straus under Laboratory Conditions (Acute Immobilisation Test – Static) Report No. S20-06895 Document No. VV-893390 Test Facility Eurofins Agroscience Services EcoTox GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	Lünsmann, V.	20/10/2021	Metalaxyl-M – Analytical Method ECO_048_03A and Validation for the Determination of Metalaxyl-M in Honey Bee Larvae Diets, Adult Honey Bee Feeding Solutions and Bumble Bee Contact Test Solutions Report No.:21 35 CRB 0059, Document No.: VV-928043 Test Facility BioChem Agrar, Germany GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	Tanzler, V.	31/12/2015	Oxathiapiprolin (DPX-QGU42) 100 g/L OD: Chronic oral toxicity to the honey bee, Apis mellifera L. (Hymenoptera, Apidae) Report No. 94441136 DuPont Study No. DuPont-41989 Syngenta Document No. VV-910995 Test Facility: Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany GLP Unpublished	N/A	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	Corteva (SYN LoA)	N/R, Please refer to data owner

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	Previously used Y/N If yes, for which data point?
KCP 5.1.2	xxxxxxxxxx	10/10/2011	Metalaxyl-M – Validation of the Multiple Residue Method QuEChERS for the Determination in Animal Matrices Report No. S11-01732 Document No. VV-400487 , CGA329351_11472 Test Facility xxxxxxxxxxxxxxxxxxxx GLP Unpublished	N	N	Expired	SYN	Y KIII 5.2
KCP 5.2.1	xxxxxxxxxx	19/11/2018	Metalaxyl-M - Independent Laboratory Validation of Analytical Method QuEChERS for the Determination of Residues of Metalaxyl-M in Animal Matrices by LC-MS/MS Report No. MM87YQ Document No. VV-470901 , CGA329351_11851 Test Facility xxxxxxxxxxxxxxxxxxxx GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCP 5.2.1	Brown, D.	15/06/2016	Metalaxyl-M – Validation of the QuEChERS Multiple Residue Method in Hops and Cocoa Beans Report No. RES-00055 Document No. VV-465427 , CGA329351_11743 Test Facility ResChem Analytical Limited GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCP 5.2.1	Burton, D.	16/08/2016	Metalaxyl-M: Independent Laboratory Validation of the QuEChERS Multiple Residue Method in Hops and Cocoa Beans Report No. YB27DB Document No. VV-465743 , CGA329351_11745 Test Facility Envigo CRS Limited GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCP 5.2.1	Fritsch S, Mohaupt R	2022	Metalaxyl-M – Extraction Efficiency Study on Leaf Lettuce, Grapes, Pepper Corn and Dried Hops in the Germany and Italy in 2021 Report No S21-03444. Syngenta File No. VV-951401 GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 5.2.1	Crook, S. Tessier, V.	01/10/2015	Metalaxyl-M - Residue Method GRM031.08A for the Determination of Metalaxyl-M (CGA329351) and Metabolites NOA409045, CGA108906 and CGA67868 in water. Non-enantiospecific method. Final determination by LC-MS/MS Report No. GRM031.08A Document No. VV-132583 , CGA329351_11693 Test Facility Syngenta - Jealott's Hill Not GLP Unpublished	N	N	N/A	SYN	N/A
KCP 5.2.1	Donald, C. Gibson, R.	27/08/2020	Oxathiapiprolin (SYN546539): Validation of the Analytical Method DuPont-30422 for the Determination of Residues of Oxathiapiprolin in Crop Matrices by LC-MS/MS Report No. 231693 Document No. VV-870136 Test Facility Charles River Laboratories Edinburgh, Ltd. GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	Y Please refer to Data point column
KCP 5.2.1	Ford, K.	15/12/2020	Oxathiapiprolin – Honey Residue Study on Spring Oilseed Rape in Northern and Southern Europe in 2020 Report No. CEMR-9533 Document No. VV-885771 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	Y Please refer to Data point column
KCP 5.2.1	xxxxxxxx	30/03/2016	Metalaxyl-M – Independent Laboratory Validation of Analytical Method GRM031.06A for the Determination of Metalaxyl-M and Structurally Related Metabolites as the Common Moiety 2,6-Dimethylaniline (CGA72649) in Animal Fat Report No. S16-00573 Document No. VV-463097 , CGA329351_11737 Test Facility xxxxxxxxxxxxxxxxxxxxxxxx GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column

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	Previously used Y/N If yes, for which data point?
KCP 5.2.1	Link, T.	12/02/2016	Metalaxyl-M – Independent Laboratory Validation of Analytical Method GRM031.08A for the Determination of Metalaxyl-M (CGA329351) and its Metabolites NOA409045, CGA108906 and CGA67868 in Drinking Water Report No. IF-15/03469803-TK Document No. VV-415481 , CGA329351_11732 Test Facility SGS Germany GmbH GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCP 5.2.1	Mewis, A.	07/01/2014	Metalaxyl-M – Independent Laboratory Validation (ILV) of an Analytical Method for Determination of Residues of Metalaxyl-M in Crops Report No. S11-03712 Document No. VV-407367 , CGA329351_11643 Test Facility Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCP 5.2.1	xxxxxxx	10/10/2011	Metalaxyl-M – Validation of the Multiple Residue Method QuEChERS for the Determination in Animal Matrices Report No. S11-01732 Document No. VV-400487 , CGA329351_11472 Test Facility xxxxxxx GLP Unpublished	N	N	Expired	SYN	Y Please refer to Data point column
KCP 5.2.2	Mechelke, J.	11/01/2022	Metalaxyl-M (CGA329351) – Validation of Analytical QuEChERS Method for the Determination of Residues of Metalaxyl-M in Peppercorn and Honey by LC-MS/MS, J. Mechelke (2022) Report number 20210433 Document No. VV-936304 Test Facility IES, Switzerland GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 5.2.2	Jooß, S., Leibing F., Tussetschläger, S.	27/04/2022	Metalaxyl-M - ILV of Analytical QuEChERS Method for the Determination of Residues of Metalaxyl-M in Honey and Peppercom by LC-MS/MS Report number S21-08274 Document No. VV-948185 Test Facility Eurofins Agroscience Services, Germany GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.2.2	xxxxxxx	19/11/2018	Metalaxyl-M - Independent Laboratory Validation of Analytical Method QuEChERS for the Determination of Residues of Metalaxyl-M in Animal Matrices by LC-MS/MS Report No. MM87YQ Document No. VV-470901 , CGA329351_11851 Test Facility xxxxxxxxxx GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCP 5.2.2	xxxxxxx	30/03/2016	Metalaxyl-M – Independent Laboratory Validation of Analytical Method GRM031.06A for the Determination of Metalaxyl-M and Structurally Related Metabolites as the Common Moiety 2,6-Dimethylaniline (CGA72649) in Animal Fat Report No. S16-00573 Document No. VV-463097 , CGA329351_11737 Test Facility xxxxxxxx GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCP 5.2.2	xxxxxxx	2022	Method Validation of Oxathiapiprolin in Body Fluids Report No. S22-02422 Document No. 220385 xxxxxxx GLP Unpublished	N/A	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	Corteva (SYN LoA)	N/R, Please refer to data owner

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	Previously used Y/N If yes, for which data point?
KCP 5.2.2	Mechelke, J	11/01/2022	Metalaxyl-M (CGA329351) – Validation of Analytical QuEChERS Method for the Determination of Residues of Metalaxyl-M in Peppercorn and Honey by LC-MS/MS, J. Mechelke (2022) Report number 20210433 Document No. VV-936304 Test Facility IES, Switzerland GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.2.2	Jooß, S., Leibing F., Tussetschläger, S	27/04/2022	Metalaxyl-M - ILV of Analytical QuEChERS Method for the Determination of Residues of Metalaxyl-M in Honey and Peppercorn by LC-MS/MS Report number S21-08274 Document No. VV-948185 Test Facility Eurofins Agroscience Services, Germany GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.2.2	xxxxxxx	10/10/2011	Metalaxyl-M – Validation of the Multiple Residue Method QuEChERS for the Determination in Animal Matrices Report No. S11-01732 Document No. VV-400487 , CGA329351_11472 Test Facility xxxxxxx GLP Unpublished	N	N	Expired	SYN	Y Please refer to Data point column
KCP 5.2.3	xxxxxxx	10/10/2011	Metalaxyl-M – Validation of the Multiple Residue Method QuEChERS for the Determination in Animal Matrices Report No. S11-01732 Document No. VV-400487 , CGA329351_11472 Test Facility xxxxxxx GLP Unpublished	N	N	Expired	SYN	Y Please refer to Data point column
KCP 6.1	Apahidean, A.	01/12/2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF Report No. ROANZF9102021 Document No. VV-944371 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.1	Apahidean, A.	01/12/2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF Report No. ROANZF9012021 Document No. VV-944370 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Apahidean, A.	14/12/2021	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor - 2021 Report No. ROANZF9342021 Document No. VV-944372 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Bertin, B.	24/02/2021	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. FRBEZF0352020 Document No. VV-938002 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Cap, N.	30/09/2019	Profiling & registration of EXF16939C / EXF16956C in onion in EAME 2019 Report No. BEKHZF9082019 Document No. VV-937960 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Cap, N.	09/03/2021	EAME Registration of A23109A and A22773A for lettuce against bremia in FIELD in EU – 2020 Report No. BEKHZF0012020 Document No. VV-937958 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.1	Carstens, H.	09/01/2020	EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Report No. DEDSZF1452019 Document No. VV-937988 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Chatelier, B.	04/11/2020	EAME Registration of A23109A and A22773A for lettuce against bremia in FIELD in EU – 2020 Report No. FRQUZF0232020 Document No. VV-938007 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Commandeur, I.	16/12/2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF Report No. NLA2ZF9032021 Document No. VV-944367 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Commandeur, I.	07/11/2019	Profiling & registration of EXF16956C / EXF16939C (OXTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Report No. NLZWZF9142019 Document No. VV-938046 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Darwich, S.	21/12/2020	EAME Registration of A23109A against Peronospora parasitica in brassicae in EAME 2020 Report No. BEINZF0032020 Document No. VV-937957 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.1	De Vries, H.	27/11/2019	Profiling & registration of EXF16939C / EXF16956C (OXTF + MFX) in onion in EAME 2019 Report No. NLZWZF9062019 Document No. VV-938042 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	De Vries, H.	18/01/2021	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. NLZWZF9042020 Document No. VV-938041 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Evenhuis, B.	30/10/2020	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. NLPPZF9032020 Document No. VV-938040 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Hoitink, R.	18/08/2020	EAME Registration of A23109A against Peronospora parasitica in brassicae in EAME 2020 Report No. NLZWZF9092020 Document No. VV-938045 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Ingenerf, M.	10/12/2021	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor - 2021 Report No. DEANZF9292021 Document No. VV-944357 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.1	Jarecka-Boncela, A.	02/12/2019	EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Report No. PLIWZF1102019 Document No. VV-938058 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Jarecka-Boncela, A.	08/01/2020	Profiling & registration of EXF16956C / EXF16939C (OXTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Report No. PLIWZF1122019 Document No. VV-938059 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Jarecka-Boncela, A.	31/05/2020	EAME Registration of A23109A (OXTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Report No. PLIWZF1072020 Document No. VV-938057 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Jarecka-Boncela, A.	31/05/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against bremia in FIELD in EU – 2020 Report No. PLIWZF1022020 Document No. VV-938054 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Jarecka-Boncela, A.	15/09/2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. PLIWZF1042020 Document No. VV-938056 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.1	Jatczak, K.	29/08/2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF Report No. PLANZF9042021 Document No. VV-944368 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Krosschell, A.	02/11/2020	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. NLEXZF9022020 Document No. VV-938037 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Martin, T.	18/11/2020	EAME Registration of A23109A (OXTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Report No. DEFMZ1022020 Document No. VV-937990 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Matusiak, J.	03/12/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against brexia in FIELD in EU – 2020 Report No. PLDSZF5172020 Document No. VV-938050 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Matusiak, J.	30/11/2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. PLDSZF5202020 Document No. VV-938051 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.1	Mesange, C.	18/11/2020	EAME Registration of A23109A and A22773A for lettuce against brexia in FIELD in EU – 2020 Report No. FRCMZ0322020 Document No. VV-938003 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Otrhalkova, P.	04/11/2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. CZITZF1052020 Document No. VV-937986 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Ripaud, H.	20/12/2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia GH 2019 Report No. FRQUZF9312019 Document No. VV-938009 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Ripaud, H.	03/11/2020	EAME Registration of A23109A and A22773A for lettuce against brexia in GH in EU – 2020 Report No. FRQUZF0262020 Document No. VV-938008 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Ruppert, R.	10/10/2019	Profiling & registration of EXF16956C / EXF16939C (OXTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Report No. DEDSZF5572019 Document No. VV-937989 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.1	Slowiak, K.	13/12/2019	EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Report No. PLBCZF1082019 Document No. VV-938048 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Szymanska, B.	20/11/2019	Profiling & registration of EXF16939C / EXF16956C (OXTP + MFX) in onion in EAME 2019 Report No. PLUPZF1022019 Document No. VV-938063 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Toth, F.	04/01/2022	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor - 2021 Report No. SKANZF9332021 Document No. VV-944373 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Venneman, S.	25/11/2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia GH 2019 Report No. BESKZF9112019 Document No. VV-937974 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Venneman, S.	09/12/2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia GH 2019 Report No. BESKZF9122019 Document No. VV-937975 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.1	Venneman, S.	02/12/2020	EAME Registration of A23109A and A22773A for lettuce against brexia in GH in EU – 2020 Report No. BESKZF0062020 Document No. VV-937966 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Venneman, S.	07/12/2020	EAME Registration of A23109A and A22773A for lettuce against brexia in GH in EU – 2020 Report No. BESKZF0052020 Document No. VV-937965 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Venneman, S.	09/12/2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 Report No. BESKZF9102019 Document No. VV-937973 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Venneman, S.	10/12/2020	EAME Registration of A23109A and A22773A for lettuce against brexia in FIELD in EU – 2020 Report No. BESKZF0042020 Document No. VV-937964 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Viard, J.	21/07/2021	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor - 2021 Report No. FRANZF9312021 Document No. VV-944360 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.1	Wachowiak, P.	12/10/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against bremia in FIELD in EU – 2020 Report No. PLEUZF1072020 Document No. VV-938052 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Willocq, B.	20/11/2019	Profiling & registration of EXF16939C / EXF16956C in onion in EAME 2019 Report No. FRSTZF9082019 Document No. VV-938028 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.1	Zappe, C.	29/12/2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF Report No. DEANZF9072021 Document No. VV-944356 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Bertin, B.	24/02/2021	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. FRBEZF0352020 Document No. VV-938002 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Bertin, B.	22/09/2020	EAME Registration of A23109A and A22773A for Leek against Phytophthora porri 2020 Report No. FRBEZF0272020 Document No. VV-938001 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Cap, N.	30/09/2019	Profiling & registration of EXF16939C / EXF16956C in onion in EAME 2019 Report No. BEKHZF9082019 Document No. VV-937960 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Cap, N.	09/03/2021	EAME Registration of A23109A and A22773A for lettuce against brexia in FIELD in EU – 2020 Report No. BEKHZF0012020 Document No. VV-937958 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Cap, N.	07/01/2020	Profiling & registration of EXF16939C/EXF16956C against P. porri in leek in EAME 2019 Report No. BEKHZF9112019 Document No. VV-937961 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Carstens, H.	09/01/2020	EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Report No. DEDSZF1452019 Document No. VV-937988 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Chatelier, B.	04/11/2020	EAME Registration of A23109A and A22773A for lettuce against brexia in FIELD in EU – 2020 Report No. FRQUZF0232020 Document No. VV-938007 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Commandeur, I.	07/11/2019	Profiling & registration of EXF16956C / EXF16939C (OXTTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Report No. NLZWZF9142019 Document No. VV-938046 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Darwich, S.	21/12/2020	EAME Registration of A23109A against Peronospora parasitica in brassicae in EAME 2020 Report No. BEINZF0032020 Document No. VV-937957 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	De Vries, H.	27/11/2019	Profiling & registration of EXF16939C / EXF16956C (OXTTP + MFX) in onion in EAME 2019 Report No. NLZWZF9062019 Document No. VV-938042 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	De Vries, H.	18/01/2021	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. NLZWZF9042020 Document No. VV-938041 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	De Vries, H.	02/12/2019	Profiling & registration of EXF16939C / EXF16956C (OXTTP + MFX) in onion in EAME 2019 Report No. NLZWZF9072019 Document No. VV-938043 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Descamps, A.	31/03/2020	Profiling & registration of EXF16939C/EXF16956C against P. porri in leek in EAME 2019 Report No. FRSTZF9152019 Document No. VV-938029 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Evenhuis, B.	30/10/2020	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. NLPPZF9032020 Document No. VV-938040 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Hoitink, R.	18/08/2020	EAME Registration of A23109A against Peronospora parasitica in brassicae in EAME 2020 Report No. NLZWZF9092020 Document No. VV-938045 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Hoitink, R.	06/01/2021	EAME Registration of A23109A against Peronospora farinosa in spinach in 2020 - FIELD Report No. NLZWZF9082020 Document No. VV-938044 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Jarecka-Boncêla, A.	02/12/2019	EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Report No. PLIWZF1102019 Document No. VV-938058 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Jarecka-Boncela, A.	08/01/2020	Profiling & registration of EXF16956C / EXF16939C (OXTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Report No. PLIWZF1122019 Document No. VV-938059 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Jarecka-Boncela, A.	31/05/2020	EAME Registration of A23109A (OXTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Report No. PLIWZF1072020 Document No. VV-938057 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Jarecka-Boncela, A.	31/05/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against brexia in FIELD in EU – 2020 Report No. PLIWZF1022020 Document No. VV-938054 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Jarecka-Boncela, A.	15/09/2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. PLIWZF1042020 Document No. VV-938056 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Jarecka-Boncela, A.	28/10/2021	EAME tank mixes efficacy of OXTP (+AZT or +MFX) in onion against DM in open field in PL- 2021 Report No. PLIWZF1032021 Document No. VV-938055 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Jarecka-Boncela, A.	28/10/2021	EAME tank mixes efficacy of OXTP (+AZT or +MFX) in onion against DM in open field in PL- 2021 Report No. PLIWZF1012021 Document No. VV-938053 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Kasperek, M.	16/12/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against brexia in FIELD in EU – 2020 Report No. PLSYZF1012020 Document No. VV-938061 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Kozłowska, A.	13/09/2021	EAME tank mixes efficacy of OXTP (+AZT or +MFX) in onion against DM in open field in PL- 2021 Report No. PLPBZF1022021 Document No. VV-938060 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Krosschell, A.	02/11/2020	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. NLEXZF9022020 Document No. VV-938037 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Krosschell, A.	18/02/2021	EAME Registration A23109A (OXTP+MFX) and A22773A (OXTP+AZT) for Leek against Phytophthora porri 2020 Report No. NLEXZF9112020 Document No. VV-938039 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Martin, T.	18/11/2020	EAME Registration of A23109A (OXTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Report No. DEFMZ1022020 Document No. VV-937990 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Matusiak, J.	03/12/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against brexia in FIELD in EU – 2020 Report No. PLDSZF5172020 Document No. VV-938050 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Matusiak, J.	30/11/2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. PLDSZF5202020 Document No. VV-938051 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Matusiak, J.	07/12/2020	EAME Registration of A23109A (OXTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Report No. PLDSZF5132020 Document No. VV-938049 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Mesange, C.	18/11/2020	EAME Registration of A23109A and A22773A for lettuce against brexia in FIELD in EU – 2020 Report No. FRCMZ0322020 Document No. VV-938003 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Neukermans, J.	08/11/2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 Report No. BEKHZF9122019 Document No. VV-937962 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Neukermans, J.	29/11/2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 Report No. BEKHZF9132019 Document No. VV-937963 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Otrhalkova, P.	04/11/2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. CZITZF1052020 Document No. VV-937986 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Peters, E.	12/01/2021	EAME Registration of A23109A against Peronospora farinosa in spinach in 2020 - FIELD Report No. NLEXZF9092020 Document No. VV-938038 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Rivet, J.	06/03/2020	Profiling & registration of EXF16939C/EXF16956C against P. porri in leek in EAME 2019 Report No. FREPZF9292019 Document No. VV-938006 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Rivet, J.	15/12/2020	EAME Registration of A23109A against <i>Peronospora farinosa</i> in spinach in 2020 - FIELD Report No. FREPZF0252020 Document No. VV-938004 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Rivet, J.	19/02/2021	EAME Registration of A23109A and A22773A for Leek against <i>Phytophthora porri</i> 2020 Report No. FREPZF0272020 Document No. VV-938005 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Ruppert, R.	10/10/2019	Profiling & registration of EXF16956C / EXF16939C (OXTTP + MFX) against <i>Peronospora brassicae</i> in brassicae in EAME 2019 Report No. DEDSZF5572019 Document No. VV-937989 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Slowiak, K.	13/12/2019	EAME Profiling & registration OXTTP+AZT - Orondis Evo (A22773A) and OXTTP+MFX for Lettuce against <i>Bremia</i> in the field 2019 Report No. PLBCZF1082019 Document No. VV-938048 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Slowiak, K.	25/11/2019	Profiling & registration of EXF16956C / EXF16939C (OXTTP + MFX) against <i>Peronospora brassicae</i> in brassicae in EAME 2019 Report No. PLBCZF1022019 Document No. VV-938047 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Szymanska, B.	20/11/2019	Profiling & registration of EXF16939C / EXF16956C (OXTTP + MFX) in onion in EAME 2019 Report No. PLUPZF1022019 Document No. VV-938063 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Szymanska, B.	23/11/2020	EAME Registration of A23109A (OXTTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Report No. PLUPZF1182020 Document No. VV-938065 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Szymanska, B.	20/11/2019	Profiling & registration of EXF16956C / EXF16939C (OXTTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Report No. PLUPZF1012019 Document No. VV-938062 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Szymanska, B.	17/09/2020	EAME Registration OXTTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. PLUPZF1162020 Document No. VV-938064 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Venneman, S.	09/12/2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 Report No. BESKZF9102019 Document No. VV-937973 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Venneman, S.	10/12/2020	EAME Registration of A23109A and A22773A for lettuce against Bremia in FIELD in EU – 2020 Report No. BESKZF0042020 Document No. VV-937964 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Venneman, S.	03/12/2019	Profiling & registration of EXF16956C / EXF16939C against Peronospora farinosa in spinach in EAME 2019 - FIELD Report No. BESKZF9132019 Document No. VV-937976 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Venneman, S.	08/05/2020	Profiling & registration of EXF16939C/EXF16956C against P. porri in leek in EAME 2019 Report No. BESKZF9072019 Document No. VV-937972 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Venneman, S.	03/11/2020	EAME Registration of A23109A and A22773A for Leek against Phytophthora porri 2020 Report No. BESKZF0122020 Document No. VV-937970 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Venneman, S.	07/12/2020	EAME Registration of A23109A against Peronospora farinosa in spinach in 2020 - FIELD Report No. BESKZF0132020 Document No. VV-937971 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Venneman, S.	11/02/2021	EAME Registration of A23109A and A22773A for Leek against Phytophthora porri 2020 Report No. BESKZF0112020 Document No. VV-937969 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Wachowiak, P.	12/10/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against brexia in FIELD in EU – 2020 Report No. PLEUZF1072020 Document No. VV-938052 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Willocq, B.	20/11/2019	Profiling & registration of EXF16939C / EXF16956C in onion in EAME 2019 Report No. FRSTZF9082019 Document No. VV-938028 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Aversa, A.	2020	EAME Profiling OXTP+AZT - Orondis Evo (A22773) for Lettuce against Bremia GH 2019 Syngenta Italia S.p.A ITSOZF1002019 GEP Unpublished VV-938034	N	Y	New study never submitted before to this country	SYN	N
KCP 6.2	Oriol, B.	2020	EAME Registration of A23109A and A22773A for lettuce against brexia in GH in EU – 2020 SynTech Research France SAS FRSYZF0332020 GEP Unpublished VV-938030	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.2	Spreckelsen G.	2021	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against brexia in GH in EU – 2020 Syntech Research Portugal PTSTZF0152020 GEP Unpublished VV-938066	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Bertin, B.	24/02/2021	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. FRBEZF0352020 Document No. VV-938002 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Bertin, B.	22/09/2020	EAME Registration of A23109A and A22773A for Leek against Phytophthora porri 2020 Report No. FRBEZF0272020 Document No. VV-938001 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Cap, N.	30/09/2019	Profiling & registration of EXF16939C / EXF16956C in onion in EAME 2019 Report No. BEKHZF9082019 Document No. VV-937960 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Cap, N.	09/03/2021	EAME Registration of A23109A and A22773A for lettuce against brexia in FIELD in EU – 2020 Report No. BEKHZF0012020 Document No. VV-937958 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Cap, N.	07/01/2020	Profiling & registration of EXF16939C/EXF16956C against P. porri in leek in EAME 2019 Report No. BEKHZF9112019 Document No. VV-937961 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Carstens, H.	09/01/2020	EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Report No. DEDSZF1452019 Document No. VV-937988 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Chatelier, B.	04/11/2020	EAME Registration of A23109A and A22773A for lettuce against bremia in FIELD in EU – 2020 Report No. FRQUZF0232020 Document No. VV-938007 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Commandeur, I.	07/11/2019	Profiling & registration of EXF16956C / EXF16939C (OXTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Report No. NLZWZF9142019 Document No. VV-938046 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Darwich, S.	21/12/2020	EAME Registration of A23109A against Peronospora parasitica in brassicae in EAME 2020 Report No. BEINZF0032020 Document No. VV-937957 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	De Vries, H.	27/11/2019	Profiling & registration of EXF16939C / EXF16956C (OXTP + MFX) in onion in EAME 2019 Report No. NLZWZF9062019 Document No. VV-938042 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	De Vries, H.	18/01/2021	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. NLZWZF9042020 Document No. VV-938041 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	De Vries, H.	02/12/2019	Profiling & registration of EXF16939C / EXF16956C (OXTP + MFX) in onion in EAME 2019 Report No. NLZWZF9072019 Document No. VV-938043 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Descamps, A.	31/03/2020	Profiling & registration of EXF16939C/EXF16956C against P. porri in leek in EAME 2019 Report No. FRSTZF9152019 Document No. VV-938029 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Evenhuis, B.	30/10/2020	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. NLPPZF9032020 Document No. VV-938040 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Hoitink, R.	18/08/2020	EAME Registration of A23109A against <i>Peronospora parasitica</i> in brassicae in EAME 2020 Report No. NLZWZF9092020 Document No. VV-938045 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Hoitink, R.	06/01/2021	EAME Registration of A23109A against <i>Peronospora farinosa</i> in spinach in 2020 - FIELD Report No. NLZWZF9082020 Document No. VV-938044 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Jarecka-Boncela, A.	02/12/2019	EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against <i>Bremia</i> in the field 2019 Report No. PLIWZF1102019 Document No. VV-938058 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Jarecka-Boncela, A.	08/01/2020	Profiling & registration of EXF16956C / EXF16939C (OXTP + MFX) against <i>Peronospora brassicae</i> in brassicae in EAME 2019 Report No. PLIWZF1122019 Document No. VV-938059 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Jarecka-Boncela, A.	31/05/2020	EAME Registration of A23109A (OXTP + MFX) against <i>Peronospora parasitica</i> in brassicae in EAME 2020 Report No. PLIWZF1072020 Document No. VV-938057 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Jarecka-Boncela, A.	31/05/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against brexia in FIELD in EU – 2020 Report No. PLIWZF1022020 Document No. VV-938054 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Jarecka-Boncela, A.	15/09/2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. PLIWZF1042020 Document No. VV-938056 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Jarecka-Boncela, A.	28/10/2021	EAME tank mixes efficacy of OXTP (+AZT or +MFX) in onion against DM in open field in PL- 2021 Report No. PLIWZF1032021 Document No. VV-938055 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Jarecka-Boncela, A.	28/10/2021	EAME tank mixes efficacy of OXTP (+AZT or +MFX) in onion against DM in open field in PL- 2021 Report No. PLIWZF1012021 Document No. VV-938053 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Kasperek, M.	16/12/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against brexia in FIELD in EU – 2020 Report No. PLSYZF1012020 Document No. VV-938061 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Kozłowska, A.	13/09/2021	EAME tank mixes efficacy of OXTP (+AZT or +MFX) in onion against DM in open field in PL- 2021 Report No. PLPBZF1022021 Document No. VV-938060 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Krosschell, A.	02/11/2020	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU - 2020 Report No. NLEXZF9022020 Document No. VV-938037 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Krosschell, A.	18/02/2021	EAME Registration A23109A (OXTP+MFX) and A22773A (OXTP+AZT) for Leek against Phytophthora porri 2020 Report No. NLEXZF9112020 Document No. VV-938039 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Martin, T.	18/11/2020	EAME Registration of A23109A (OXTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Report No. DEFMZFF1022020 Document No. VV-937990 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Matusiak, J.	03/12/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against brexia in FIELD in EU – 2020 Report No. PLDSZF5172020 Document No. VV-938050 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Matusiak, J.	30/11/2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. PLDSZF5202020 Document No. VV-938051 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Matusiak, J.	07/12/2020	EAME Registration of A23109A (OXTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Report No. PLDSZF5132020 Document No. VV-938049 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Mesange, C.	18/11/2020	EAME Registration of A23109A and A22773A for lettuce against bremia in FIELD in EU – 2020 Report No. FRCMZ0322020 Document No. VV-938003 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Neukermans, J.	08/11/2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 Report No. BEKHZF9122019 Document No. VV-937962 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Neukermans, J.	29/11/2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 Report No. BEKHZF9132019 Document No. VV-937963 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Otrhalkova, P.	04/11/2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. CZITZF1052020 Document No. VV-937986 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Peters, E.	12/01/2021	EAME Registration of A23109A against Peronospora farinosa in spinach in 2020 - FIELD Report No. NLEXZF9092020 Document No. VV-938038 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Rivet, J.	06/03/2020	Profiling & registration of EXF16939C/EXF16956C against P. porri in leek in EAME 2019 Report No. FREPZF9292019 Document No. VV-938006 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Rivet, J.	15/12/2020	EAME Registration of A23109A against Peronospora farinosa in spinach in 2020 - FIELD Report No. FREPZF0252020 Document No. VV-938004 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Rivet, J.	19/02/2021	EAME Registration of A23109A and A22773A for Leek against Phytophthora porri 2020 Report No. FREPZF0272020 Document No. VV-938005 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Ruppert, R.	10/10/2019	Profiling & registration of EXF16956C / EXF16939C (OXTTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Report No. DEDSZF5572019 Document No. VV-937989 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Slowiak, K.	13/12/2019	EAME Profiling & registration OXTTP+AZT - Orondis Evo (A22773A) and OXTTP+MFX for Lettuce against Bremia in the field 2019 Report No. PLBCZF1082019 Document No. VV-938048 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Slowiak, K.	25/11/2019	Profiling & registration of EXF16956C / EXF16939C (OXTTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Report No. PLBCZF1022019 Document No. VV-938047 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Szymanska, B.	20/11/2019	Profiling & registration of EXF16939C / EXF16956C (OXTTP + MFX) in onion in EAME 2019 Report No. PLUPZF1022019 Document No. VV-938063 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Szymanska, B.	23/11/2020	EAME Registration of A23109A (OXTTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Report No. PLUPZF1182020 Document No. VV-938065 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Szymanska, B.	20/11/2019	Profiling & registration of EXF16956C / EXF16939C (OXTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Report No. PLUPZF1012019 Document No. VV-938062 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Szymanska, B.	17/09/2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Report No. PLUPZF1162020 Document No. VV-938064 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Venneman, S.	09/12/2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 Report No. BESKZF9102019 Document No. VV-937973 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Venneman, S.	10/12/2020	EAME Registration of A23109A and A22773A for lettuce against bremia in FIELD in EU – 2020 Report No. BESKZF0042020 Document No. VV-937964 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Venneman, S.	03/12/2019	Profiling & registration of EXF16956C / EXF16939C against Peronospora farinosa in spinach in EAME 2019 - FIELD Report No. BESKZF9132019 Document No. VV-937976 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Venneman, S.	08/05/2020	Profiling & registration of EXF16939C/EXF16956C against P. porri in leek in EAME 2019 Report No. BESKZF9072019 Document No. VV-937972 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Venneman, S.	03/11/2020	EAME Registration of A23109A and A22773A for Leek against Phytophthora porri 2020 Report No. BESKZF0122020 Document No. VV-937970 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Venneman, S.	07/12/2020	EAME Registration of A23109A against Peronospora farinosa in spinach in 2020 - FIELD Report No. BESKZF0132020 Document No. VV-937971 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Venneman, S.	11/02/2021	EAME Registration of A23109A and A22773A for Leek against Phytophthora porri 2020 Report No. BESKZF0112020 Document No. VV-937969 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Wachowiak, P.	12/10/2020	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against brexia in FIELD in EU – 2020 Report No. PLEUZF1072020 Document No. VV-938052 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Willocq, B.	20/11/2019	Profiling & registration of EXF16939C / EXF16956C in onion in EAME 2019 Report No. FRSTZF9082019 Document No. VV-938028 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Aversa, A.	2020	EAME Profiling OXTP+AZT - Orondis Evo (A22773) for Lettuce against Bremia GH 2019 Syngenta Italia S.p.A ITSOZF1002019 GEP Unpublished VV-938034	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Oriol. B.	2020	EAME Registration of A23109A and A22773A for lettuce against bremia in GH in EU – 2020 SynTech Research France SAS FRSYZF0332020 GEP Unpublished VV-938030	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Spreckelsen G.	2021	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against bremia in GH in EU – 2020 Syntech Research Portugal PTSTZF0152020 GEP Unpublished VV-938066	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.1	Espinosa A.	2020	EAME Registration OXTP+MFX (A23109A) and MFX+CU (A15605D) on Lettuce - Crop safety trials 2020 BIOTEK Agricluture España S.L ESBTZF0052020 GEP Unpublished VV-937992	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.1	Soto Espinosa F.	2020	EAME Registration OXTP+MFX (A23109A) and MFX+CU (A15605D) on Lettuce - Crop safety trials 2020 FS Trials S.L ESFSZF0092020 GEP Unpublished VV-937995	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.3	Cap, N.	07/01/2020	Profiling & registration of EXF16939C/EXF16956C against P. porri in leek in EAME 2019 Report No. BEKHZF9112019 Document No. VV-937961 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.3	Espinosa A.	2020	EAME Registration OXTP+MFX (A23109A) and MFX+CU (A15605D) on Lettuce - Crop safety trials 2020 BIOTEK Agriculuture España S.L ESBTZF0052020 GEP Unpublished VV-937992	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.3	Soto Espinosa F.	2020	EAME Registration OXTP+MFX (A23109A) and MFX+CU (A15605D) on Lettuce - Crop safety trials 2020 FS Trials S.L ESFSZF0092020 GEP Unpublished VV-937995	N	Y	New study never submitted before to this country	SYN	N
KCP 6.4.4	Cap, N.	29/03/2021	Registration trials with A23109A - taint test on leek in EU - 2020 Report No. BEKHZF0042020 Document No. VV-937959 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 6.4.4	Furlan, A.	12/10/2020	Registration trials with A23109A - taint test on leek in EU - 2020 Report No. FRSTZF0192020 Document No. VV-938027 Test Facility Syngenta Limited GEP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.5.2	Jones K.	2020/2021	Oxathiapiprolin/metalaxyl-M DC (A23109A) - Phytotoxicity to Non-Target Plants Screening Test, Final Report Amendment 1 AgroChemex Ltd. Study Number: ACE-20-109 GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 6.5.2	Breedt C.	2020	A23109A – The Effectiveness of the Spray Tank Cleaning Procedure, Final Report Syngenta Crop Protection AG Analytical Development & Product Chemistry Report Number: 450796 GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 7.1.1	xxxxxxx	12/01/2021	Metalaxyl-M / Oxathiapiprolin Metalaxyl-M / Oxathiapiprolin DC (A23109A) - Acute Oral Toxicity Study in Rats (Up and Down Procedure) Report No. 20/131-001P Document No. VV-888460 Test Facility xxxxxxx GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 7.1.2	xxxxxxx.	16/12/2020	Metalaxyl-M/Oxathiapiprolin DC (A23109A) – Acute Dermal Toxicity Study in Rats Report No. 20/131-002P Document No. VV-885797 Test Facility xxxxxxx GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 7.1.3	xxxxxxxxx	16/08/2021	Metalaxyl-M / Oxathiapiprolin DC (A23109A) - Acute Inhalation Toxicity Study (Nose-Only) in Rats Report No. 20/131-004P Document No. VV-915563 Test Facility xxxxxxxx GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 7.1.4	xxxxxxxxx	26/05/2021	Metalaxyl-M / Oxathiapiprolin DC (A23109A) - Primary Skin Irritation Study in Rabbits Report No. 20/131-006N Document No. VV-904073 Test Facility xxxxxxxx GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 7.1.4	Toth-Gonzalez, K.	14/10/2020	Metalaxyl-M / Oxathiapiprolin DC (A23109A) – In Vitro Skin Irritation Test in the EPISKIN™ Model Report No. 20/131-043B Document No. VV-876289 Test Facility Charles River Laboratories Hungary, Kft. GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 7.1.5	xxxxxxxxx	23/07/2020	Metalaxyl-M / Oxathiapiprolin DC (A23109A) - Acute Eye Irritation Study in Rabbits Report No. 19/269-005N Document No. VV-868398 Test Facility xxxxxxxx GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 7.1.6	xxxxxxxxx	09/12/2020	Metalaxyl-M / Oxathiapiprolin DC (A23109A) – Skin Sensitisation Local Lymph Node Assay Report No. 2119700 Document No. VV-885070 Test Facility xxxxxxxx GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 7.3	Blackstock, C. Morrison, C.	27/07/2021	Metalaxyl-M/Oxathiapiprolin DC (A23109A) - The In Vitro Percutaneous Absorption of Radiolabelled Metalaxyl-M and Radiolabelled Oxathiapiprolin in Concentrate Formulation and Two In-Use Dilutions Through Human Split-Thickness Skin Report No. 787369 Document No. VV-913056 Test Facility Charles River Laboratories Edinburgh, Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 9.1.1	Crabtree, G.	20/04/2021	Formation Fraction of SYN546520 from CGA329351 Degradation in Aerobic Soils Report No. 3202751 Document No. VV-899796 Test Facility Smithers (ERS), Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 9.1.1	Patel, M.	01/03/2022	Metalaxyl-M – FOCUS Kinetics Evaluation of Three Laboratory Soils to Derive Formation Fraction of SYN546520 from NOA409045 Report No. RAJ1429B Document No. VV-902577 Test Facility Syngenta Limited Not GLP Unpublished	N	N	N/A	SYN	-
KCP 9.1.1	Patel, M.	16/12/2021	CGA108906 – Kinetic evaluation of Formation Fraction with EFSA endpoints Report No. RAJ1447B Document No. VV-933662 Test Facility Syngenta Limited Not GLP Unpublished	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 9.2.4	Cooke, J.	04/03/2022	Metalaxyl-M - A Leaching Assessment for Parent and Metabolites NOA409045, CGA67868 and SYN546520 Using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Central Zone Report No. 0608830-GW3 Document No. VV-942658 Test Facility ERM Not GLP Unpublished	N	N	N/A	SYN	-
KCP 9.2.4	Cooke, J.	04/03/2022	Oxathiapiprolin - A Leaching Assessment for Parent and Metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 Using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Central Zone Report No. 0608830-GW4 Document No. VV-942664 Test Facility ERM Not GLP Unpublished	N	N	N/A	SYN	-
KCP 10.1.1.1	xxxxxxx	28/01/2021	Oxathiapiprolin/Metalaxyl-M DC (A23109A) – An Acute Oral Toxicity Study with the Northern Bobwhite using a Sequential Testing Procedure Report No. 528B-605 Document No. VV-891190 Test Facility xxxxxx GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 10.1.2 (KCP 7.1.1)	xxxxxxx	12/01/2021	Metalaxyl-M / Oxathiapiprolin Metalaxyl-M / Oxathiapiprolin DC (A23109A) - Acute Oral Toxicity Study in Rats (Up and Down Procedure) Report No. 20/131-001P Document No. VV-888460 Test Facility xxxxxx GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 10.2.1	xxxxxxx	26/02/2021	Oxathiapiprolin/Metalaxyl-M DC (A23109A) - Toxicity to the Rainbow Trout Oncorhynchus mykiss under Laboratory Conditions (Acute Toxicity Test – Static) Report No. S20-06894 Document No. VV-893371 Test Facility xxxxxxxx GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 10.2.1	Schuler, L.	26/02/2021	Oxathiapiprolin/metalaxyl-M DC (A23109A) - Toxicity to the Water Flea Daphnia magna Straus under Laboratory Conditions (Acute Immobilisation Test – Static) Report No. S20-06895 Document No. VV-893390 Test Facility Eurofins Agroscience Services EcoTox GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.2.1	Schuler, L.	12/04/2021	Oxathiapiprolin/Metalaxyl-M DC (A23109A) - Toxicity to the Single Cell Green Alga Raphidocelis subcapitata Korshikov under Laboratory Conditions Report No. S20-06896 Document No. VV-898484 Test Facility Eurofins Agroscience Services EcoTox GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.3.1.1	Franke, M.	25/01/2021	Oxathiapiprolin/Metalaxyl-M DC (A23109A) - Acute Toxicity to the Honeybee Apis mellifera L. under Laboratory Conditions Report No. 21 48 BAA 0002 Document No. VV-892684 Test Facility BioChem agrar GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.3.1.1.1	Amsel, K.	10/01/2022	Oxathiapiprolin/Metalaxyl-M DC (A23109A) - Acute toxicity to the bumblebee Bombus ter-restris L. under laboratory conditions Report No. 21 48 BBA 0033 Document No. VV-936483 Test Facility BioChem agrar GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 10.3.1.2	Dressler, K.	11/11/2020	Oxathiapiprolin/Metalaxyl-M DC (A23109A) - Chronic toxicity to the honey bee <i>Apis mellifera</i> L. in a 10-day continuous laboratory feeding study Report No. 20 48 BAC 0044 Document No. VV-896929 Test Facility BioChem agrar GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.3.1.3	Schmidt, K.	19/03/2021	Oxathiapiprolin/Metalaxyl-M DC (A23109A) – Repeated Exposure of the Honey Bee Larvae (<i>Apis mellifera</i> L.) under Laboratory Conditions (until Adult Emergence up to Day 22) Report No. 20 48 BLC 0044 Document No. VV-895633 Test Facility BioChem agrar GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.3.2.1	Fallowfield, L.	11/12/2020	Oxathiapiprolin/metalaxyl-M DC (A23109A) – A Rate-Response Laboratory Study to Determine the Effects of Fresh Residues on the Predatory Mite <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) Report No. SYN-20-71 Document No. VV-887718 Test Facility Mambo-Tox, Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.3.2.1	Stevens, J.	03/12/2020	Oxathiapiprolin/Metalaxyl-M DC (A23109A) – A Rate-Response Laboratory Study to Determine the Effects of Fresh Residues on the Parasitic Wasp <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) Report No. SYN-20-72 Document No. VV-887720 Test Facility Mambo-Tox, Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 10.3.2.2	Fallowfield, L.	16/03/2021	Oxathiapiprolin/metalaxyl-M DC (A23109A) – A Rate-Response Extended Laboratory Study to Determine the Effects of Fresh Residues on the Predatory Mite Typhlodromus pyri (Acari: Phytoseiidae) Report No. SYN-20-77 Document No. VV-895497 Test Facility Mambo-Tox, Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.3.2.2	Stevens, J.	16/03/2021	Oxathiapiprolin/Metalaxyl-M DC (A23109A) – A Rate-Response Extended Laboratory Study of the Effects of Fresh Residues on the Parasitic Wasp Aphidius rhopalosiphi (Hymenoptera, Braconidae) Report No. SYN-20-78 Document No. VV-895493 Test Facility Mambo-Tox, Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.3.2.2	Tew, G.	01/06/2021	Oxathiapiprolin/metalaxyl-M DC (A23109A) - A Rate-Response Extended Laboratory Study of the Effects of Freshly Treated Substrate on the Rove Beetle, Aleochara bilineata (Coleoptera, Staphylinidae) Report No. SYN-20-79 Document No. VV-905353 Test Facility Mambo-Tox, Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.3.2.2	Vaughan, R.	05/05/2021	Oxathiapiprolin/Metalaxyl-M DC (A23109A) – A Rate-Response Extended Laboratory Study to Evaluate the Effects of Fresh Residues on the Green Lacewing, Chrysoperla carnea (Neuroptera, Chrysopidae) Report No. SYN-20-80 Document No. VV-902193 Test Facility Mambo-Tox, Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 10.4.1	Friedrich, S.	17/02/2021	Oxathiapiprolin/metalaxyl-M DC (A23109A) - Acute Toxicity to the Earthworm Eisenia andrei in Artificial Soil Report No. 21 48 TEA 0001 Document No. VV-892721 Test Facility BioChem agrar GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.4.1.1	Friedrich, S.	19/02/2021	Oxathiapiprolin/metalaxyl-M DC (A23109A) - Sublethal Effects on the Reproduction of the Earthworm Eisenia andrei in Artificial Soil Report No. 21 48 TEC 0005 Document No. VV-892682 Test Facility BioChem agrar GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.4.1.2	Friedrich, S.	04/02/2021	Oxathiapiprolin/metalaxyl-M DC (A23109A) - Effects on the Reproduction of the Collembolan Folsomia candida Report No. 21 48 TCC 0003 Document No. VV-891167 Test Facility BioChem agrar GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.4.1.2	Schulz, L.	15/01/2021	Oxathiapiprolin/metalaxyl-M DC (A23109A) - Effects on the Reproduction of the Predatory Mite Hypoaspis aculeifer Report No. 21 48 THC 0003 Document No. VV-890311 Test Facility BioChem agrar GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.5	Schulz, L.	24/02/2021	Oxathiapiprolin/Metalaxyl-M DC (A23109A) – Effects on the Activity of Soil Microflora (Nitrogen and Carbon Transformation Tests) Report No. 21 48 SMO 0002 Document No. VV-894279 Test Facility BioChem agrar GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCP 10.6.2	Jones, K.	26/01/2021	Oxathiapiprolin/metalaxyl-M DC (A23109A) - Phytotoxicity to Non-Target Plants Screening Test Report No. ACE-20-109 Document No. VV-890173 Test Facility AgroChemex, Ltd GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 5.4.2	xxxxxxx	12/08/2014	CGA62826 - Oral (Gavage) Mouse Micronucleus Test Report No. BFI0255 Document No. VV-410510 , CGA062826_10006 Test Facility xxxxxxx GLP Unpublished	Y	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	N
KCA1 5.4.2	xxxxxxx	08/06/2015	NOA409045 - Oral (Gavage) Mouse Micronucleus Test Report No. BFI0257 Document No. VV-28599 , NOA409045_10012 Test Facility xxxxxxx GLP Unpublished	Y	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCA1 5.4.2	xxxxxxx	27/01/2015	Metalaxyl-M - Oral (Gavage) Mouse Micronucleus Test Report No. BFI0262 Document No. VV-411540 , CGA329351_11683 Test Facility xxxxxxx GLP Unpublished	Y	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCA1 5.4.2	xxxxxxx	15/09/2017	CGA226048 - Oral (Gavage) Mouse Micronucleus Test Report No. BFI0633 Document No. VV-468462 , CGA226048_10000 Test Facility xxxxxxx GLP Unpublished	Y	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCA1 6.1	Baumy, G.	09/03/2021	Metalaxyl-M – Storage Stability of Residues of Metalaxyl-M in Crop Matrices Stored Frozen for up to Two Years Report No. RNB19-00020 - INT Document No. VV-894456 Test Facility SGS France - Laboratoire de Rouen GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D)	SYN	N Y Please refer to Data point column

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	Previously used Y/N If yes, for which data point?
KCA1 6.3.1	Meyer, M. Poperechna, N.	24/06/2021	Oxathiapiprolin and Metalaxyl-M - Residue Study on Broccoli in Germany, Hungary, Poland and the United Kingdom 2020 Report No. IF20-05335380 Document No. VV-908189 Test Facility SGS Institut Fresenius GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.1	Yozgatli, H. Breyer, N.	13/06/2014	Metalaxyl-M - Residue study on Cauliflower in the United Kingdom and Northern France in 2013 Report No. S13-03434 Document No. VV-407968 , A13947A_11297 Test Facility Eurofins - Dr Specht & Partner GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.2	Brown, S.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and metalaxyl-M in Kale from Trials conducted in NEU in 2020 Report No. RES-00256 Document No. VV-901782 Test Facility ResChem Analytical Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.3	Ford, K.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Residue Study on Cabbage in Northern France, Poland, Hungary and Poland in 2020 Report No. CEMR-9523 Document No. VV-901921 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.4	Brown, S.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and metalaxyl-M in Brussels Sprouts from Trials conducted in NEU in 2020 Report No. RES-00257 Document No. VV-901790 Test Facility ResChem Analytical Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCA1 6.3.5	Brown, S.	29/04/2021	Oxathiapiprolin / Metalaxyl-M - Determination of residues of Oxathiapiprolin and metalaxyl-M in Lettuce from trials conducted in NEU in 2020 Report No. RES-00259 Document No. VV-901318 Test Facility ResChem Analytical Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.5	Brown, S.	13/04/2022	Metalaxyl-M – Determination of residues of Metalaxyl-M in Lettuce from Trials conducted in NEU in 2021 Report No. RES-00332 Document No. VV-946819 Test Facility ResChem Analytical Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.5	Fritsch S	04/03/2020	Metalaxyl-M - Residue Study on Open Leaf Lettuce in Germany in 2019. Report No. S19-02726 Document No. VV-749044 Syngenta AG, Basel, Switzerland GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.5	Lakaschus S, Fritsch S	18/04/2019	Metalaxyl-M - Residue Study on Open Leaf Lettuce in the United Kingdom, Northern France and Germany in 2018. Report No. S18-04345 Document No. VV-471900 Syngenta AG, Basel, Switzerland GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA 6.3.1	Brown, S.	29/04/2021	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and Metalaxyl-M in Protected Lettuce from Trials conducted in France, Poland, Italy and Spain in 2020. Report No RES-00258 Document No VV-901190 GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCA 6.3.1	Cairns, S	11/06/2014	Residue Study with Metalaxyl-M (CGA 329351) on Protected Lettuce in Northern France and the United Kingdom in 2013. Report No 34802 Document No VV-408194 Test Facility: Charles River GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA 6.3.1	Cairns, S	13/06/2014	Residue Study with Metalaxyl-M (CGA 329351) on Protected Lettuce in Southern France and Italy in 2013 Report No 34798 Document No VV-408195 Test Facility: Charles River GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA 6.3.1	Cairns, S	29/04/2015	Residue Study with Metalaxyl-M (CGA 329351) on Protected Lettuce in the United Kingdom in 2014 Report No 35637 Document No VV-412447 Test Facility: Charles River GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.7	Kuhne, R.	08/07/1998	CGA 329351 + Mancozeb (ASF 21), WP 68, A-9407 A, Onions, Switzerland Report No. 2338/97 Document No. VV-357405 , CGA329351/0905 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	N
KCA1 6.3.7	Kuhne, R.	08/07/1998	CGA 329351 + Mancozeb (ASF 21), WP 68, A-9407 A, Onions, Switzerland Report No. 2340/97 Document No. VV-357408 , CGA329351/0906 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	N

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	Previously used Y/N If yes, for which data point?
KCA1 6.3.7	Kuhne, R.	09/07/1998	CGA 329351 + ASF 41 (Chlorothalonil / CGA 329351 + ASF 21 (Mancozeb), SC 537.5/WP68, A-9652 B/A-9407 A, Onions, Spain, United Kingdom Report No. 116/97 Document No. VV-376089 , CGA329351/0914 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	N
KCA1 6.3.7	Kuhne, R.	09/09/1999	Residue Study with Metalaxyl-M (CGA 329351) + Chlorothalonil (ASF 41) and Metalaxyl-M (CGA 329351) + Mancozeb (ASF 21) in or on Onions in Switzerland Report No. 2077/98 Document No. VV-312825 , CGA329351/1138 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	N
KCA1 6.10	Knabe, S.	12/02/2021	Metalaxyl-M - Honey Residue Study on Spring Oilseed Rape in Northern Europe in 2020 Report No. S20-03602 Document No. VV-881362 Test Facility Eurofins Agroscience Services EcoTox GmbH GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	N Y Please refer to Data point column
KCA1 8.1.1.3	xxxxxxx	15/01/1996	The reproductive toxicity test of CGA 277476 technical in northern bobwhite, colinus virginianus Report No. 029401 Document No. VV-352227 , CGA277476/0292 Test Facility xxxxxxxx GLP Unpublished	Y	N	Expired	SYN	N
KCA1 8.1.1.3	xxxxxxx	15/01/1996	The reproductive toxicity test of CGA 215944 technical in northern bobwhite, Colinus virginianus Report No. 029502 Document No. VV-369024 , CGA215944/0344 Test Facility xxxxxxxx GLP Unpublished	Y	N	Expired	SYN	N

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	Previously used Y/N If yes, for which data point?
KCA1 8.1.1.3	xxxxxxx	07/05/1996	The reproductive toxicity test of CGA 24705 in Northern Bobwhite (Colinus virginianus) Report No. 029508 Document No. VV-371001 , CGA24705/2591 Test Facility xxxxxxxx GLP Unpublished	Y	N	Expired	SYN	N
KCA1 8.1.1.3	xxxxxxx	09/07/1998	The reproductive toxicity test of CGA 293343 technical with the northern bobwhite (Colinus virginianus) Report No. 029518 Document No. VV-376393 , CGA293343/0653 Test Facility xxxxxxxx GLP Unpublished	Y	N	Expired	SYN	N
KCA1 8.3.1.2	Kling, A.	06/06/2018	Metalaxyl-M SL (A13947A) – Assessment of Effects on the Adult Honey Bee, Apis mellifera L., in a 10 Day Chronic Feeding Test under Laboratory Conditions Report No. S15-00380 Document No. VV-414721 , A13947A_11449 Test Facility Eurofins Agrosience Services EcoChem GmbH GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCA1 8.3.1.3	Eckert, J.	14/01/2016	Metalaxyl-M SL (A13947A) – Honey Bee (Apis mellifera L.) Larval Toxicity Test (Repeated Exposure) Report No. S15-02457 Document No. VV-415529 , A13947A_11455 Test Facility Eurofins Agrosience Services GmbH GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (A15605D - Ridomil Gold R)	SYN	Y Please refer to Data point column
KCA2 6.1.1	Ford, K.	20/10/2021	Oxathiapiprolin - Honey Residue Study on Winter Oilseed Rape in Northern and Southern Europe in 2021 Report No. CEMR-9822 Document No. VV-924794 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	Y	New study never submitted before to this country Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	N Y Please refer to Data point column

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	Previously used Y/N If yes, for which data point?
KCA2 6.3.1	Mahlo, C. Wolfgarten, E.	30/04/2021	Oxathiapiprolin and Metalaxyl-M - Residue Study on Cauliflower in Germany, Poland, the United Kingdom and Denmark in 2020 Report No. IF20-05336777 Document No. VV-901124 Test Facility SGS Institut Fresenius GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA2 6.3.1	Meyer, M. Poperechna, N.	24/06/2021	Oxathiapiprolin and Metalaxyl-M - Residue Study on Broccoli in Germany, Hungary, Poland and the United Kingdom 2020 Report No. IF20-05335380 Document No. VV-908189 Test Facility SGS Institut Fresenius GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA2 6.3.2	Brown, S.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and metalaxyl-M in Kale from Trials conducted in NEU in 2020 Report No. RES-00256 Document No. VV-901782 Test Facility ResChem Analytical Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA2 6.3.3	Ford, K.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Residue Study on Cabbage in Northern France, Poland, Hungary and Poland in 2020 Report No. CEMR-9523 Document No. VV-901921 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA2 6.3.4	Brown, S.	06/05/2021	Oxathiapiprolin/Metalaxyl-M – Determination of residues of Oxathiapiprolin and metalaxyl-M in Brussels Sprouts from Trials conducted in NEU in 2020 Report No. RES-00257 Document No. VV-901790 Test Facility ResChem Analytical Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N

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	Previously used Y/N If yes, for which data point?
KCA2 6.3.6	Ford, K.	05/05/2021	Oxathiapiprolin/Metalaxyl-M – Residue Study on Leek in Northern France, Poland, United Kingdom and Germany in 2020 Report No. CEMR-9521 Document No. VV-901936 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA2 6.3.7	Hampton, M.	14/09/2015	Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Cucumber Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations- - USA, 2014 Report No. TK0221427 81123 Document No. VV-511306 , A20941A_50004 Test Facility The Carringers, Inc. GLP Unpublished	N	Y	New study never submitted before to this country Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	N Y Please refer to Data point column
KCA2 6.3.8	Hampton, M.	21/09/2015	Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Brassica Head and Stem Vegetables Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations - USA, 2014 Report No. TK0221426 81122 Document No. VV-511308 , A20941A_50006 Test Facility The Carringers, Inc. GLP Unpublished	N	Y	New study never submitted before to this country Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	N Y Please refer to Data point column
KCA2 6.3.9	Hampton, M.	08/10/2015	Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Tobacco Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations - USA, 2014 Report No. 81125 TK0221432 Document No. VV-511264 , A20941A_50008 Test Facility The Carringers, Inc. GLP Unpublished	N	Y	New study never submitted before to this country Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	N Y Please refer to Data point column

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	Previously used Y/N If yes, for which data point?
KCA2 6.3.7	Hampton, M.	14/09/2015	Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Cucumber Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations- - USA, 2014 Report No. TK0221427 81123 Document No. VV-511306 , A20941A_50004 Test Facility The Carringers, Inc. GLP Unpublished	N	Y	New study never submitted before to this country Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	N Y Please refer to Data point column
KCA2 6.3.8	Hampton, M.	21/09/2015	Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Brassica Head and Stem Vegetables Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations - USA, 2014 Report No. TK0221426 81122 Document No. VV-511308 , A20941A_50006 Test Facility The Carringers, Inc. GLP Unpublished	N	Y	New study never submitted before to this country Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	N Y Please refer to Data point column
KCA2 6.3.9	Hampton, M.	08/10/2015	Oxathiapiprolin OD (A20941A) and Oxathiapiprolin SC (A21008A) - Magnitude of the Residues in or on Tobacco Raw Agricultural Commodities Resulting from Foliar Applications of OD and SC Formulations - USA, 2014 Report No. 81125 TK0221432 Document No. VV-511264 , A20941A_50008 Test Facility The Carringers, Inc. GLP Unpublished	N	Y	New study never submitted before to this country Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	N Y Please refer to Data point column
KCA2 6.3.10	Hampton, M.	08/10/2015	Oxathiapiprolin SC (A21008A) and Oxathiapiprolin OD (A20941A) - Magnitude of the Residues in or on Potato Raw Agricultural Commodities Resulting from Soil and Foliar Applications - USA, 2014 Report No. 81124 TK0221431 Document No. VV-511262 , A21008A_50006 Test Facility The Carringers, Inc. GLP Unpublished	N	Y	New study never submitted before to this country Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	N Y Please refer to Data point column

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	Previously used Y/N If yes, for which data point?
KCA2 6.10	Ford, K.	15/12/2020	Oxathiapiprolin – Honey Residue Study on Spring Oilseed Rape in Northern and Southern Europe in 2020 Report No. CEMR-9533 Document No. VV-885771 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	Y Please refer to Data point column
KCA2 6.10	Ford, K.	20/10/2021	Oxathiapiprolin - Honey Residue Study on Winter Oilseed Rape in Northern and Southern Europe in 2021 Report No. CEMR-9822 Document No. VV-924794 Test Facility CEM Analytical Services Limited (CEMAS) GLP Unpublished	N	Y	New study never submitted before to this country Study already submitted, but evaluation ongoing (Orondis Evo A22773A)	SYN	N Y Please refer to Data point column
KCA2 8.3.1.2	Tanzler V	2015	Oxathiapiprolin (DPX-QGU42) 100 g/L OD: Chronic oral toxicity to the honey bee, <i>Apis mellifera</i> L. (Hymenoptera, Apidae) Report Number 94441136 Institut für Biologische Analytik und Consulting IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany GLP Unpublished DuPont Study No. DuPont-41989	N/A	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	Corteva (SYN LoA)	N/R, Please refer to data owner
KCA2 8.3.1.3	Oberrauch S	2017	Oxathiapiprolin (DPX-QGU42) technical: Honey bee (<i>Apis mellifera</i> L.) 22 day larval toxicity test (repeated exposure) Report Number S17-01639 Eurofins Agrosience Services EcoChem GmbH / Eurofins Agrosience Services Ecotox GmbH, Eutinger Str. 24, 75223 Niefern-Öschelbronn, Germany GLP Unpublished DAS Study No. DuPont-48606	N/A	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	Corteva (Syngenta LoA)	N/R, Please refer to data owner

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

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	Previously used Y/N If yes, for which data point?
CA 1.8 (IIA 1.8) [Previously evaluated in DAR July 1999]	Burkhard N.	1995a	Manufacturing Process - CGA 329351 Ciba- Geigy Ltd., Basle, Process Description, 11.12.1995a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished Not GLP CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-
CA 1.9 (IIA 1.9) CA 1.10 (IIA 1.10) [Previously evaluated in DAR July 1999]	Burkhard N.	1995b	Purity and By-products of techn. a.i. Ciba-Geigy Ltd., Basle, Data-Sheet, 13.12..1995b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished Not GLP CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-
CA 1.10 (IIA 1.10) [Previously evaluated in DAR July 1999]	Stulz J.	1995	List of by-products, Ciba-Geigy Muenchwilten AG, Muenchwilten, 05.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished Not GLP CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-
CA 1.11 (IIA 1.11) [Previously evaluated in DAR July 1999]	Ceresa C.	1995	Purity of test material used in ecotoxicity tests Ciba-Geigy Ltd., Basle, 20.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished Not GLP Syngenta File No CGA329351/2184 (VV-14853) CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 1.11 (IIA 1.11) [Previously evaluated in DAR July 1999]	Kreuzer A.	1995	Report on nitrosamines, Ciba-Geigy Muenchwilten AG, Muenchwilten, Rep. N° 38553, 11.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0085 (VV-379000) CONFIDENTIAL INFORMATION	N	N	Expired on 10/1/2012	SYN	-
CA 1.11 (IIA 1.11) [Previously evaluated in DAR July 1999]	Schneider B.	1995	Report on chemical composition (5 batches), Ciba-Geigy Muenchwilten AG, Muenchwilten, Rep. N° 38555, 13.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0084 (VV-378999) CONFIDENTIAL INFORMATION	N	N	Expired on 10/1/2012	SYN	-
CA 1.11 (IIA 1.11) [Previously evaluated in DAR July 1999]	Stutz W.	1995	Dioxine Statement CGA 329351 Ciba-Geigy Muenchwilten AG, Muenchwilten, Statement, 18.05.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished Not GLP Syngenta File No CGA329351/0001 (VV-416964) CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-
CA 1.11 (IIA 1.11.1)	Voellmin S.	2012	Metalaxyl-M tech. - Analysis of five representative batches produced at CABB AG, Pratteln, Switzerland Syngenta Syngenta Crop Protection, Muenchwilten, Switzerland, 123948 GLP, not published Syngenta File No CGA329351_11487 (VV-401964) This is CONFIDENTIAL INFORMATION	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 1.11 (IIA 1.11.2) [Previously evaluated in DAR July 1999]	Maier W.	1995	Purity of test material used in toxicity tests Syngenta Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 1.11 _04 Not GLP, not published Syngenta File No CGA329351/2185 (VV-14854) This is CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-
CA 1.11 (IIA 1.11.2) [Previously evaluated in DAR July 1999]	Rodler M.	1988	Analytical certificate - CGA 48988 - batch EN 603107 Syngenta Ciba-Geigy, Ltd., CH-4333, Munchwilen, Switzerland, Not GLP, not published Syngenta File No CGA048988_11206 (VV-134520) This is CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-
CA 1.11 IIA 1.11.2 [Previously evaluated in DAR July 1999]	Kobayashi K.	1982	13-Week Subacute Toxicity Study of CGA-48988 in Rats Syngenta Crop Protection AG, Basel, Switzerland Nippon Experimental Medical Research Institute Co. Ltd., Ohdo, Japan, GLP, not published Syngenta File No CGA48988/5095 (VV-332387) This is CONFIDENTIAL INFORMATION	N	N	Expired on 10/1/2012	SYN	-
CA 1.11 (IIA 1.11.2) [Previously evaluated in DAR July 1999]	Niggli H.	1982	Metalaxyl - CGA48988 techn. EN 32212 (tox. reserve) Syngenta, 5205 Not GLP, not published Syngenta File No CGA048988_11207 This is CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-
CA 1.11 (IIA 1.11.2)	Micheletti, S	2012	Metalaxyl-M EU Document J Supplement; DEREK Analysis; Syngenta Document No. CGA329351_11492 (VV-127192) Not GLP Not published This is CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 1.11 (IIA 1.11.2)	Winkler, G.	1996	Acute oral toxicity in the rat of CGA 363736 (By-product of CGA 329 351), Ciba-Geigy Ltd., Stein, Switzerland; Rep. Nr. 953142, 05.03.1996 Owned by Novartis Crop Protection AG, Basel, Switzerland Submitted by Novartis Crop Protection AG, Basel, Switzerland GLP unpublished This is CONFIDENTIAL INFORMATION Syngenta File No CGA363736/0001 (VV-353774)	N	Y	New study never submitted before to this country	SYN	-
CA 1.11 (IIA 1.11.2)	Deparade, E	1996	<i>Salmonella and Escherichia /mammalian-microsome mutagenicity test. Test number: 953 143; Test substance: CGA 363736 (By-product of CGA 329351).</i> <i>Ciba-Geigy Ltd., Stein, Switzerland; Rep. Nr. 953143, 03.04.1996</i> <i>Owned by Novartis Crop Protection AG, Basel, Switzerland</i> <i>Submitted by Novartis Crop Protection AG, Basel, Switzerland</i> <i>GLP</i> <i>Unpublished</i> <i>Syngenta File No CGA363736/0002 (VV-353787)</i> <i>This is CONFIDENTIAL INFORMATION</i>	N	Y	New study never submitted before to this country	SYN	-
CA 1.11 (IIA 1.11.2)	Deparade, E	2000	<i>Salmonella and Escherichia /mammalian-microsome mutagenicity test. Test number: 19 993 124; Test substance: CGA 226 048 (By-product of CGA 329351).</i> <i>Novartis Crop Protection Limited, Switzerland; Rep. Nr. 19 993 124, 29.02.2000</i> <i>Owned by Novartis Crop Protection AG, Basel, Switzerland</i> <i>Submitted by Novartis Crop Protection AG, Basel, Switzerland</i> <i>GLP</i> <i>Unpublished</i> <i>Syngenta File No CGA226048/0002 (VV-310086)</i> <i>This is CONFIDENTIAL INFORMATION</i>	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 1.11 (IIA 1.11.2)	Clay, P	2004	Metalaxyl-M impurity CGA 226 048: L5178Y TK+/- Mouse Lymphoma Mutation Assay. Central Toxicology Laboratory, Alderley Park Macclesfield Cheshire, UK. CTL Study Number VV0319 No, issue date: 22 December 2004. Unpublished. Sponsor reference T004822-04 Owned by Syngenta Crop Protection, Mönchwil, Switzerland, 123948 GLP, not published Syngenta File No GLP Unpublished Syngenta File No CGA226048/0003 (VV-332513) This is CONFIDENTIAL INFORMATION	N	Y	New study never submitted before to this country	SYN	-
CA 1.11 (IIA 1.11.2)	Fox, V	2005	Metalaxyl-M impurity CGA 226 048: In vitro cytogenetic assay in Human Lymphocytes. Central Toxicology Laboratory - Alderley Park Macclesfield, Cheshire UK. Sponsor Reference T013126-04; CTL Test substance reference number: Y13192/001; CTL Study number SV1276; Document number CTL/SV1276/REG/REPT; Owned by Syngenta Crop Protection, Mönchwil, Switzerland, 123948 GLP, not published Syngenta File No CGA226048/0004 (VV-332850) GLP Unpublished This is CONFIDENTIAL INFORMATION	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 1.11 (IIA 1.11.2)	Stulz J.	1995	Report on Chemical Composition Syngenta Ciba-Geigy, Ltd., CH-4333, Munchwilen, Switzerland, Not GLP, not published Syngenta File No CGA329351/1929 (VV-381141) This is CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-
CA 1.11 (IIA 1.11.2)	Schneider B.	1995	Report on Chemical Composition Syngenta Ciba-Geigy, Ltd., CH-4333, Munchwilen, Switzerland, Not GLP, not published Syngenta File No CGA329351/0084 (VV-378999) This is CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-
CA 4.1.1 (IIA 4.2.3) [Previously evaluated in DAR July 1999]	Schneider B.	1995	Analytical method - CGA 329351 by-products and supplementary tests Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Munchwilen AG, Munchwilen, Switzerland, AK-183/2 Not GLP, not published Syngenta File No CGA329351/0082 (VV-127859) This is CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-
CA 4.1.1 (IIA 4.2.3) [Previously evaluated in DAR July 1999]	Schneider B.	1995a	Report on validation of analytical method - AK-183/2 Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Munchwilen AG, Munchwilen, Switzerland, 38418 GLP, not published Syngenta File No CGA329351/0088 (VV-379002) This is CONFIDENTIAL INFORMATION	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.1 (IIA 4.2.3) [Previously evaluated in DAR July 1999]	Oggenfuss P.	1996	Confirmation of structures of by-products for CGA 329351 by mass spectroscopy Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Munchwilen AG, Munchwilen, Switzerland, Not GLP, not published Syngenta File No CGA329351/0430 (VV-381425) This is CONFIDENTIAL INFORMATION	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 2.0 IIA 2	Bourgeois W.	1995a	Meier P., Rätz V., Schneider B., Purification report Ciba-Geigy Muenchwilten AG, Muenchwilten, Rep. N° AMS 758 / 101, 15.11.1995a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished Not GLP Syngenta File No CGA329351/0063 (VV-378998)	N	N	N/A	SYN	-
CA 2.0 IIA 2	Burkhard N.	1997	Metalaxyl-M/CGA 329351 : Content of R-enantiomer in test material used for physical/chemical tests Novartis Crop Protection AG, Basle, 20.08.1997 Owned by : Novartis Crop Protection AG Submitted by : Novartis Crop Protection AG Unpublished Not GLP	N	N	N/A	SYN	-
CA 2.1 IIA 2.1.1 [Previously evaluated in DAR July 1999]	Geoffroy A.	1994a	Report on melting / freezing temperature Ciba-Geigy Ltd., Basle, Rep. N° PP-94/45P.MPR, 28.12.1994a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0043 (VV-284150)	N	N	Expired on 10/1/2012	SYN	-
CA 2.1 IIA 2.1.2 IIA 2.1.3 [Previously evaluated in DAR July 1999]	Das R.	1994a	Report on boiling point / boiling range Ciba-Geigy Muenchwilten AG, Muenchwilten, Rep. N° 26165, 02.01.1994a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0034 (VV-284143)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 2.2 IIA 2.3.1 [Previously evaluated in DAR July 1999]	Geoffroy A.	1994b	Report on vapour pressure curve Ciba-Geigy Ltd., Basle, Rep. N° PP-94/45P.VPC, 29.12.1994b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0044 (VV-284069)	N	N	Expired on 10/1/2012	SYN	-
CA 2.2 IIA 2.3.2 [Previously evaluated in DAR July 1999]	Burkhard N.	1995	Henry's Law Constant Ciba-Geigy Ltd., Basle, Data-Sheet, 31.03.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd Unpublished Not GLP Syngenta File No CGA329351/0062 (VV-293353)	N	N	N/A	SYN	-
CA 2.3 IIA 2.4 [Previously evaluated in DAR July 1999]	Das R.	1994c	Report on general physico-chemical properties (pure active ingredient), Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26171, 11.11.1994c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0021 (VV-284140)	N	N	Expired on 10/1/2012	SYN	-
CA 2.3 IIA 2.4 [Previously evaluated in DAR July 1999]	Das R	1994d	Report on general physico-chemical properties (technical grade active ingredient), Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26831, 11.11.1994d Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0020 (VV-377952)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 2.4 IIA 2.5.1 [Previously evaluated in DAR July 1999]	Bourgeois W.	1994a	Report on spectra (CGA 329351) Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 22171, 11.07.1994a Owned by : Ciba-Geigy Ltd. Unpublished GLP Submitted by : Ciba-Geigy Ltd. Syngenta File No CGA329351/0013 (VV-284130)	N	N	Expired on 10/1/2012	SYN	-
CA 2.4 IIA 2.5.2 [Previously evaluated in DAR July 1999]	Schneider B.	1995	Report on spectra (CGA 72649) Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 34015, 07.08.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA72649/0001 (VV-340228)	N	N	Expired on 10/1/2012	SYN	-
CA 2.5 IIA 2.6 [Previously evaluated in DAR July 1999]	Stulz J.	1994a	Report on water solubility Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26169, 17.10.1994a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0016 (VV-284132)	N	N	Expired on 10/1/2012	SYN	-
CA 2.6 IIA 2.7 [Previously evaluated in DAR July 1999]	Stulz J.	1994b	Report on solubility in organic solvents Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26833, 30.11.1994b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0022 (VV-284141)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 2.7 IIA 2.8 [Previously evaluated in DAR July 1999]	Stulz J.	1994c	Report on octanol/water partition coefficient Ciba-Geigy Muenchwilten AG, Muenchwilten, Rep. N° 26168, 02.11.1994c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0018 (VV-284137)	N	N	Expired on 10/1/2012	SYN	-
CA 2.8 IIA 2.9.4 [Previously evaluated in DAR July 1999]	Jäkel K.	1995	Report on dissociation constant in water Ciba-Geigy Ltd., Basle, Rep. N° PP-94 / 45P.DCW, 02.01.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0041 (VV-284146)	N	N	Expired on 10/1/2012	SYN	-
CA 2.9 IIA 2.11 [Previously evaluated in DAR July 1999]	Schürch H.	1994a	Report on auto-ignition temperature of liquids Ciba-Geigy Ltd., Basle, Rep N° PP-94/45T.AFG, 09.12.1994a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0048 (VV-284079)	N	N	Expired on 10/1/2012	SYN	-
CA 2.10 IIA 2.12 [Previously evaluated in DAR July 1999]	Schürch H.	1994b	Report on determination of flashpoint Ciba-Geigy Ltd., Basle, Rep N° PP-94/45T.FLP, 09.12.1994b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0046 (VV-284075)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 2.11 IIA 2.13 [Previously evaluated in DAR July 1999]	Schürch H.	1994c	Report on explosive properties Ciba-Geigy Ltd., Basle, Rep N° PP-94/45T.EXP, 09.12.1994c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0047 (VV-284077)	N	N	Expired on 10/1/2012	SYN	-
CA 2.12 IIA 2.14 [Previously evaluated in DAR July 1999]	Ryser M.	1994	Report on surface tension af aqueous solutions Ciba-Geigy Ltd., Basle, Rep N° PP-94/45T.SUR, 21.12.1994 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0042 (VV-284148)	N	N	Expired on 10/1/2012	SYN	-
CA 2.13 IIA 2.15	Jackson W.	2011	Metalaxyl-M - Oxidising properties Syngenta Syngenta Technology & Projects, Huddersfield, United Kingdom, HT11/531 GLP, not published Syngenta File No CGA329351_11458 (VV-397429)	N	Y	New study never submitted before to this country	SYN	-
CA 2.14 IIA 2.2 [Previously evaluated in DAR July 1999]	Das R.	1994b	Report on density Ciba-Geigy Muenchwilen AG, Muenchwilen, Rep. N° 26166, 09.11.1994b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0017 (VV-284135)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 7.2.1 IIA 2.9.1 [Previously evaluated in DAR July 1999]	Ellgehausen H.	1996	Hydrolysis of 14C-labelled CGA 329351 under laboratory conditions Ciba-Geigy Ltd., Basle, Report N° 95EH05, 03.01.1996 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0330 (VV-372644)	N	N	Expired on 10/1/2012	SYN	-
CA 7.2.1 IIA 2.9.2 [Previously evaluated in DAR July 1999]	Ellgehausen H.	1995	Aqueous photolysis of 14C CGA 329351 under artificial sunlight conditions Ciba-Geigy Ltd., Basle, Report N° 95EH04, 20.12.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd Unpublished GLP Syngenta File No CGA329351/0329 (VV-377898)	N	N	Expired on 10/1/2012	SYN	-
CA 7.2.1 IIA 2.9.3 [Previously evaluated in DAR July 1999]	Phaff R.	1995	Rate and quantum yield of the direct phototransformation of CGA 329351 under laboratory conditions in water Ciba-Geigy Ltd., Basle, Rep.N° 59RP02, 26.10.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished GLP Syngenta File No CGA329351/0297 (VV-377631)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 7.2.1 IIA 2.10 [Previously evaluated in DAR July 1999]	Stamm E.	1995	Atmospheric oxidation of CGA 329351 by hydroxyl radicals Rate estimation Ciba-Geigy Ltd., Basle, Rep. N° 95SM06, 09.05.1995 Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished Not GLP Syngenta File No CGA329351/0072 (VV-372646)	N	N	N/A	SYN	-
CA 3 IIA 3.3	Micheletti S.	2012	Metalaxyl-M Efficacy Statement A9651D & A9642C Syngenta Crop Protection AG, Basel, Switzerland Not GLP, not published Syngenta File No CGA329351_11501	N	N	N/A	SYN	-
CA 4.1.1 CA 4.2 IIA 4.1.1 [Previously evaluated in DAR July 1999]	Schneider B.	1995a	Analytical Method CGA 329351 tech. Ciba-Geigy Muenchwilen AG, Muenchwilen, Met. N° AW-183/3, 01.12.1995a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished, not GLP Syngenta File No CGA329351/0038 (VV-125438)	N	N	N/A	SYN	-
CA 4.1.1 CA 4.2 IIA 4.1.1 [Previously evaluated in DAR July 1999]	Schneider B.	1995b	Report on Validation of Analytical Method AW-183/3 Ciba-Geigy Muenchwilen AG, Muenchwilen Rep. N° 36934, 06.12.1995b Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished, GLP Syngenta File No CGA329351/0087 (VV-284089)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.1.1 CA 4.2 IIA 4.1.2 [Previously evaluated in DAR July 1999]	Schneider B.	1995c	Analytical Method - By-Products and Supplementary Tests, Ciba-Geigy Muenchwilten AG, Muenchwilten Met. N° AK-183/2, 05.12.1995c Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished, Not GLP Syngenta File No CGA329351/0082 (VV-127859)	N	N	N/A	SYN	-
CA 4.1.1 CA 4.2 IIA 4.1.2 [Previously evaluated in DAR July 1999]	Schneider B.	1995d	Report on Validation of Analytical Method AK-183/2 Ciba-Geigy Muenchwilten AG, Muenchwilten Rep. N° 38418, 13.12.1995d Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished, GLP Syngenta File No CGA329351/0088 (VV-379002)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.1 IIA 4.1.2 [Previously evaluated in DAR July 1999]	Kreuzer A.	1995a	Report on Nitrosamines, Ciba-Geigy Muenchwilten AG, Muenchwilten Rep.N° AG-38553, 11.11.1995a Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished, GLP Syngenta File No CGA329351/0085 (VV-379000)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.1 IIA 4.1.2 [Previously evaluated in DAR July 1999]	Kreuzer, A. and Wyden, W.	1995b	Analytical Method - Nitrosamines in Agrochemicals - by chemical Cleavage / Chemiluminescence Detection, Ciba-Geigy Muenchwilten AG, Muenchwilten Met.N° AG-20/4, 12.06.1995b Owned by: Ciba-Geigy Ltd. Submitted by: Ciba-Geigy Ltd. Unpublished, not GLP Syngenta File No N/0004 (VV-340420)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.1.2 IIA 4.2.1 [Previously evaluated in DAR July 1999]	Kühne R.O.	1995b	CGA 329351 Determination of Parent Compound by Gas Chromatography; Plant Material; Ciba-Geigy Ltd., Basel; Rep. No. REM 181.01, 31.08.1995b; including attached Report on Special Study No. 127-95 (Validation of Method REM 181.01); Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished, not GLP Syngenta File No CGA329351/0216 (VV-379947)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.2.1 [Previously evaluated in DAR July 1999]	Kühne R.O.	1995c	CGA 329351, Determination of Parent Compound by Gas Chromatography; Must and Wine; Ciba-Geigy Ltd., Basel; Rep. No. REM 181.02, 31.08.1995c; including attached Report on Special Study No. 128-95 (Validation of Method REM 181.02); Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished, not GLP Syngenta File No CGA329351/0217 (VV-377634)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.2.1 [Previously evaluated in DAR July 1999]	Kühne R.O.	1995d	CGA 329351 Determination of Parent Compound by Gas Chromatography; Tobacco; Ciba-Geigy Ltd., Basel; Rep. No. REM 181.03; 31.08.1995d including attached Report on Special Study No. 129-95 (Validation of Method REM 181.03); Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished, not GLP Syngenta File No CGA329351/0218 (VV-374613)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.3	Kühne	1999	Validation data of the Method REM 181.01 (including also the version modified for use with LC-LC-MS/MS). Validation by Analysis of Fortified Specimens and Determination of Recoveries: Discussion and Evaluation of Previously Reported Results. Substrate Citrus Crops (Lemons, Mandarins, Oranges) Syngenta Crop Protection AG, Basel, Switzerland Not GLP, not published Syngenta File No CGA329351/1229 (VV-312772)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.1.2/ IIA 4.3	Kühne	1999	Validation Data of the Method REM 181.01 (Including also the version modified for use with LC-LC-MS-MS). Validation by Analysis of Fortified Specimens and Determination of Recoveries: Discussion and Evaluation of Previously Reported Results. Substrate Cotton Seeds. Syngenta Crop Protection AG, Basel, Switzerland Not GLP, not published Syngenta File No CGA329351/1230 (VV-312773)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.3	Kühne	1999	Validation Data of the Method REM 181.01 (Including also the version modified for use with LC-LC-MS-MS). Validation by Analysis of Fortified Specimens and Determination of Recoveries: Discussion and Evaluation of Previously Reported Results. Substrate Sunflower Seeds. Syngenta Crop Protection AG, Basel, Switzerland Not GLP, not published Syngenta File No CGA329351/1231 (VV-312774)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.3	Anderson L.	2005	Metalaxyl-M (CGA329351): Summary of validation data of Residue Analytical Method REM 181.01 (with determination by LC-LC-MS/MS) for the determination of residues in crops Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, T004798-04 Not GLP, not published Syngenta File No CGA329351/2052 (VV-332256)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.2.1 [Previously evaluated in addendum to DAR 2001]	Grunenwald, M.C.	1999	Confirmatory analytical method for the enantioselective determination of residues of parent metalaxyl (CGA 48988) or mefenoxam (CGA 329351) in crop substrates by chiral high performance liquid chromatography with mass spectrometric detection NovartisCrop Protection AG, 1 March 1999 Report N° 456-98 GLP, not published Novartis file N° CGA329351/5012 Syngenta File No CGA48988/5012 (VV-309533)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.1.2 IIA 4.2.1 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001a	Metalaxyl-M (CGA 329351) – Plant material : Determination of parent compound by GC (enantiospecific method). Validated with : oranges, potatoes, rape seed, tomatoes, wheat Syngenta Crop Protection AG, 19 February 2001 Report N° REM 181.06 not GLP, not published Syngenta file N° CGA329351/1463 (VV-123965)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.2 IIA 4.2.1 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001b	Validation of method REM 181.06 : validation by analysis of specimens fortified with metalaxyl-M (CGA 329351, R-enantiomer) and CGA 351920 (S-enantiomer) and determination of recoveries Syngenta Crop Protection AG, 19 February 2001 Report N° 212/00 GLP, not published Syngenta file N° CGA329351/1464 (VV-312775)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.2 IIA 4.2.1 [Previously evaluated in addendum to DAR 2001]	Pointurier, R.	2001	Independent Laboratory Validation (ILV) – Validation of method REM 181.06 (validation by analysis of fortified specimens and determination of recoveries (ILV)). Determination of metalaxyl-M (CGA 329351) and CGA 351920 by GC (enantiospecific method) Syngenta Crop Protection AG, 4 April 2001 Report N° NOV/MET/00111 GLP, not published Syngenta file N° CGA329351/1469 (VV-312112)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.2 IIA 4.3	Hill S.	2005	Residue Analytical Method For the Determination of Residues of Metalaxyl-M in Crop Samples. Final Determination by LC-MS/MS Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, REM 181.13 Not GLP, not published Syngenta File No CGA329351/2024 (VV-124441)	N	N	-	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.1.2 IIA 4.3	Hill S.	2005a	Metalaxyl-M: Validation of REM181.13, Residue Analytical Method for the Determination of Residues in Crops. Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill, Bracknell, United Kingdom, RJ3585B 04-S624 GLP, not published Syngenta File No CGA329351/2025 (VV-332241)	N	Y	New study never submitted before to this country	SYN	-
CA 4.1.2 IIA 4.3	Hill S.	2005b	Residue Analytical Method for the Determination of Residues of Metalaxyl-M in Crop Samples. Final Determination by LC-MS/MS Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, REM 181.13A Not GLP, not published Syngenta File No CGA329351/2082 (VV-125481)	N	N	-	SYN	-
CA 4.1.2 IIA 4.3	Lakaschus, S., Amann, S.	2012	Metalaxyl-M – Validation of Analytical Method GRM031.06A for the Determination of Residues of Metalaxyl-M and Structurally Related Metabolites as the Common Moiety 2,6-Dimethylaniline (CGA72649) in Animal Matrices Report No. S11-03382 Document No. VV-402332 , CGA329351_11524 Test Facility Eurofins Agrosience Services Chem GmbH GLP Unpublished	N	Y	Study already submitted, but evaluation ongoing.	SYN	-
CA 4.1.2 CA 4.2 IIA 4.3	Kühne, R.O.	2002	Foodstuff of Animal Origin. Determination of Parent Compound by LC-LC-MS/MS (REM143.03) Syngenta Crop Protection AG, Basel, Switzerland Not GLP, not published Syngenta File No CGA48988/5024 (VV-124207)	N	N	N/A	SYN	-
CA 4.1.2 CA 4.2 IIA 4.3	Kühne, R.O.	2002	Validation of Method REM 143.03. Validation by analysis of specimens of eggs, fat, meat and milk fortified with metalaxyl (CGA 48988) and determination of recoveries. (Study 217/01) Syngenta Crop Protection AG, Basel, Switzerland GLP, not published Syngenta File No CGA48988/5025 (VV-326129)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.2 IIA 4.3	Tribolet, R.	2002	Independent Laboratory Validation (ILV) of Method REM 143.03. Validation by analysis of specimens of meat and milk fortified with metalaxyl (CGA 48988) and determination of recoveries. Syngenta Crop Protection AG, Basel, Switzerland GLP, not published Syngenta File No CGA48988/5026 (VV-326179)	N	Y	New study never submitted before to this country	SYN	-
CA 4.1.2/ IIA 4.2.2 [Previously evaluated in DAR 1999]	Ramsteiner, K.	1977	Gas Chromatographic Residue Determination of CGA 48988 and its main Metabolite CGA 62826 in Soil; Ciba-Geigy Ltd., Basel, Rep. No. REM 7/77, 06.04.1977. Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished, not GLP Syngenta File No CGA48988/0603 (VV-125391)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.2.2 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2000a	Supplement to method REM 7/77 (Gas chromatographic residue determination of CGA 48988 and its main metabolite CGA 62826 in soil) – Analysis of soil specimens fortified with Metalaxyl-M (CGA 329351) and its metabolite NOA 409045 and determination of recoveries (short validation) – Description of confirmatory technique NovartisCrop Protection AG, 5 October 2000 Report N° 529/00 not GLP, not published Novartis file N° 329351/1401 Syngenta File No CGA329351/1401 (VV-23703)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.2.2 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001c	Metalaxyl-M – soil : Determination of parent compound by LC-LC-MS/MS (enantiospecific method). Validated with : surface soil Syngenta Crop Protection AG, 27 April 2001 Report N° REM 181.08 not GLP, not published Syngenta file N° CGA329351/1477 (VV-127547)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.1.2 IIA 4.2.2 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001d	Validation of method REM 181.08 : validation by analysis of specimens fortified with Metalaxyl-M (CGA 329351, R-enantiomer) and CGA 351920 (S-enantiomer) and determination of recoveries Syngenta Crop Protection AG, 23 April 2001 Report N° 207/01 GLP, not published Syngenta file N° CGA329351/1475 (VV-312776)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.2 IIA 4.2.2 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001e	Determination of acid metabolite NOA 409045 by LC-LC-MS/MS (enantiospecific method) – soil. Validated with : surface soil Syngenta Crop Protection AG, 15 May 2001 Report N° REM 181.10 not GLP, not published Syngenta file N° CGA329351/1481 (VV-380251)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.2.2 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001f	Validation of method REM 181.10 : validation by analysis of specimens fortified with NOA 409045 (R-enantiomer) and NOA 436575 (S-enantiomer) and determination of recoveries Syngenta Crop Protection AG, 14 May 2001 Report N° 209/01 GLP, not published Syngenta file N° CGA329351/1483 (VV-312777)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.2 IIA 4.2.2 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001g	CGA 329351 – Determination of metabolite CGA 108906 by LC-LC-MS/MS – soil. Validated with : surface soil Syngenta Crop Protection AG, 27 June 2001 Report N° REM 181.12 not GLP, not published Syngenta file N° CGA329351/1491 (VV-635352)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.1.2 IIA 4.2.2 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001h	Validation of method REM 181.12 : validation by analysis of specimens fortified with CGA 108906 and determination of recoveries Syngenta Crop Protection AG, 21 June 2001 Report N° 212/01 GLP, not published Syngenta file N° CGA329351/1492 (VV-326403)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.2 IIA 4.2.3 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001i	Metalaxyl-M – water : Determination of parent compound by LC-LC-MS/MS (enantiospecific method). Validated with : potable water, surface water Syngenta Crop Protection AG, 27 April 2001 Report N° REM 181.07 not GLP, not published Syngenta file N° CGA329351/1478 (VV-123966)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.2.3 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001j	Validation of method REM 181.07 : validation by analysis of specimens fortified with Metalaxyl-M (CGA 329351, R-enantiomer) and CGA 351920 (S-enantiomer) and determination of recoveries Syngenta Crop Protection AG, 6 April 2001 Report N° 206/01 GLP, not published Syngenta file N° CGA329351/1476 (VV-312779)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.2 IIA 4.2.3 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001k	Determination of acid metabolite NOA 409045 by LC-LC-MS/MS (enantiospecific method) –water. Validated with : potable water, surface water Syngenta Crop Protection AG, 15 May 2001 Report N° REM 181.09 not GLP, not published Syngenta file N° CGA329351/1480 (VV-312778)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.1.2 IIA 4.2.3 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001l	Validation of method REM 181.09 : validation by analysis of specimens fortified with NOA 409045 (R-enantiomer) and NOA 436575 (S-enantiomer) and determination of recoveries Syngenta Crop Protection AG, 14 May 2001 Report N° 208/01 GLP, not published Syngenta file N° CGA329351/1482 (VV-312780)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.2 IIA 4.2.3 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001m	CGA 329351 – Determination of metabolite CGA 108906 by LC-LC-MS/MS – water. Validated with : potable water, surface water Syngenta Crop Protection AG, 27 June 2001 Report N° REM 181.11 not GLP, not published Syngenta file N° CGA329351/1490 (VV-635353)	N	N	N/A	SYN	-
CA 4.1.2 IIA 4.2.3 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2001n	Validation of method REM 181.11 : validation by analysis of specimens fortified with CGA 108906 and determination of recoveries Syngenta Crop Protection AG, 21 June 2001 Report N° 211/01 GLP, not published Syngenta file N° CGA329351/1489 (VV-326406)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.2 IIA 4.2.3 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2000b	Residue method : Determination of parent compound (CGA 329351) and of its acid metabolite (NOA 409045, including CGA 62826) by GC in water NovartisCrop Protection AG, 11 August 2000 Report N° REM 181.05 not GLP, not published Syngenta file N° CGA329351/1388 (VV-326406)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.1.2 IIA 4.2.3 [Previously evaluated in addendum to DAR 2001]	Kühne, R.O.	2000c	Validation of method REM 181.05 : validation by analysis of specimens fortified with either Metalaxyl-M (CGA 329351), NOA 409045 or CGA 62826 and determination of recoveries NovartisCrop Protection AG, 19 July 2000 Report N° 202/00 GLP, not published Syngenta file N° CGA329351/1387 (VV-310422)	N	N	Expired on 10/1/2012	SYN	-
CA 4.1.2 IIA 4.5	Tummon O.	2005	Metalaxyl-M: Validation of an Analytical Method for the Determination of Residues of Metalaxyl-M in Water Syngenta Crop Protection AG, Basel, Switzerland Syngenta, Jealott's Hill, United Kingdom, RJ3563B 04-S622 (RAM 450-01) GLP, not published Syngenta File No CGA329351/2032 (VV-379406)	N	Y	Data protection started with 2180766 on 18.12.2019; Expiry date 18.12.2029	SYN	-
CA 4.1.2 IIA 4.2.4 [Previously evaluated in DAR 1999]	Tribolet, R.	1993	Metalaxyl, Sampling of Air and Determination of Residues of Parent Compound by Gas yes Chromatography, Ciba-Geigy Ltd., Basel, Rep. No. REM 143.02, 10.02.1993. Owned by : Ciba-Geigy Ltd. Submitted by : Ciba-Geigy Ltd. Unpublished, GLP Syngenta File No CGA48988/3352 (VV-127540)	N	N	Expired on 10/1/2012	SYN	-
CA 4.2 IIA 4.3	Weber H.	2011	Metalaxyl-M : Validation of the Multiple Residue Method QuEChERS for the Determination in Crops Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S11-01731 GLP, not published Syngenta File No CGA329351_11471 (VV-400486)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 4.2 IIA 4.3	Wiesner F., Breyer N.	2012	Metalaxyl-M - Validation of Analytical Method DFG S19 for Determination of Metalaxyl-M Residues in Crops Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S11-03698 GLP, not published Syngenta File No CGA329351_11478 (VV-401335)	N	Y	New study never submitted before to this country	SYN	-
CA 4.2 IIA 4.4	Crook S.	2008	Metalaxyl-M - Analytical Method for the Determination of Residues of Metalaxyl-M (CGA329351) and NOA409045 in Soil. Non-enantiospecific method. Final Determination by LC-MS/MS Syngenta - Jealott's Hill, Bracknell, United Kingdom Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM031.03A Not GLP, not published Syngenta File No CGA329351_11403 (VV-127701)	N	N	N/A	SYN	-
CA 4.2 IIA 4.5	Crook S.	2008a	Metalaxyl-M - Residue Method for the Determination of Metalaxyl-M (CGA329351) and Metabolites NOA409045 and CGA108906 in water. Non-enantiospecific method. Final determination by LC-MS/MS Syngenta - Jealott's Hill, Bracknell, United Kingdom Syngenta - Jealott's Hill, Bracknell, United Kingdom, GRM031.02A Not GLP, not published Syngenta File No CGA329351_11402 (VV-127696)	N	N	N/A	SYN	-
CA 4.2 IIA 4.7	Evans P.	2006	Metalaxyl-M - Validation of an Analytical Method for the Determination of Metalaxyl-M in Air Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, T003619-05-REG ; method GRM011.01A GLP, not published Syngenta File No CGA329351/2321 (VV-379739)	N	Y	Data protection started with 3979 on 30.11.2018; Expiry date 30.11.2028	SYN	-
CA 5.9 IIA 5.9	Abass, K; Reponen, P; Jalonen, J; Pelkonen, O	2007	<i>In vitro metabolism and interactions of the fungicide metalaxyl in human liver preparations</i> <i>Non-GLP, published</i> <i>Environmental Toxicology and Pharmacology (2007), 23(1), 39-47</i>	N/A	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 5.3 IIA 5.3	Al-Amoudi W.M	2012	Haematological and Biochemical Effects of Metalaxyl Fungicide on Albino Mice, Non-GLP, published American Journal of Biochemistry, 2(5): 62-66 (2012)	N/A	N	N/A	SYN	-
CA 5.8.1 IIA 5.8	Bohnenberger , S	2012	CGA92370 - Chromosome Aberration Test in Human Lymphocytes In Vitro Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1449002 GLP, not published Syngenta File No CGA092370_10003 (VV-402488)	N	Y	New study never submitted before to this country	SYN	-
CA 5.8.1 IIA 5.8	Bohnenberger , S	2014	NOA409045 - In Vitro Chromosome Aberration Test in Human Lymphocytes. Harlan Cytotest Cell Research GmbH (Harlan CCR), In den Leppsteinswiesen 19, 64380 Rossdorf, Germany. Laboratory Report No. 1591500, issue date: 10 April 2014. GLP, not published Syngenta File No NOA409045_10010 (VV-407547)	N	Y	New study never submitted before to this country	SYN	-
IIA 5.8.3	Carlson	2011	Oral (Gavage) Hershberger Bioassay of Metalaxyl in Male Rats. Charles River Laboratories Preclinical Services, Pennsylvania. Project No. 20012407. December 9, 2011. GLP, not published MRID: 48617604 Syngenta File No CGA048988_50039 (VV-506318)	Y	Y	New study never submitted before to this country	SYN	-
IIA 5.8.3	Carlson	2012	A Pubertal Development and Thyroid Function Assay of Metalaxyl by Oral Gavage in Peripubertal Male and Female Rats. Charles River Laboratories, Horsham, PA, USA. Study Number 20012408. July 17, 2012. GLP, not published MRID: 4870131. Syngenta File No CGA048988_50062 (VV-509369)	Y	Y	New study never submitted before to this country	SYN	-

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CA 5.3.2 IIA 5.3.3	Chao MW, Kim MY, Ye W, Ge J, Trudel LJ, Belanger CL, Skipper PL, Engelward BP, Tannenbaum SR, Wogan GN	2012	Genotoxicity of 2,6- and 3,5-dimethylaniline in cultured mammalian cells: the role of reactive oxygen species. Non-GLP, published Toxicol Sci.130(1):48-59, 2012	N/A	N	N/A	SYN	-
CA 5.8.1 IIA 5.8	Clay, P	2006	CGA62826 - L5178 TK+/- Mouse Lymphoma Mutation Assay Syngenta Crop Protection AG, Basel,Switzerland Central Toxicology Laboratory (CTL),Cheshire, United Kingdom, VV0350-REG GLP, not published Syngenta File No CGA329351/2318 (VV-337156)	N	Y	New study never submitted before to this country	SYN	-
CA 5.8.1 IIA 5.8	Clay, P	2001	CGA62826 CGA 108906 (Metabolite of CGA329351) - L5178Y TK+/- mouse lymphoma mutation assay Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, VV0261 /20003082 GLP, not published Syngenta File No CGA108906/0013 (VV-311524)	N	Y	New study never submitted before to this country	SYN	-
CA 5.4 IIA 5.4	Costa, C; Silva, S; Neves, J; Coelho, P; Costa, S; Laffon, B; Snawder, J; Teixeira, J.P	2011	Micronucleus Frequencies in Lymphocytes and Reticulocytes in a Pesticide-Exposed Population in Portugal Non-GLP, published Journal of Toxicology and Environmental Health, Part A: (2011), 74 (15-16), 960-970.	N/A	N	N/A	SYN	-

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CA 5.8.1 KIIA 5.8	Czich, A	2001	In vitro chromosome aberration test in Chinese hamster V79 cells with CGA108906 tech. (Metabolite of CGA329351) Syngenta Crop Protection AG, Basel, Switzerland RCC Cytotest Cell Research GmbH, Rossdorf, Germany, 684301 GLP, not published Syngenta File No CGA108906/0012 (VV-311721)	N	Y	New study never submitted before to this country	SYN	-
KCA 5.8.1	Deparade, E	1997	CGA62826 tech. Salmonella and Escherichia/mammalian-microsome mutagenicity study 963102 Novartis Crop Protection, Basel, Switzerland GLP Unpublished	Y	N	Expired on 10/1/2012	SYN	-
KCA 5.8.1	Winkler, G	1996	CGA62826 Acute Oral Toxicity in the rat (limit test) 963100 Ciba-Geigy Ltd., 4332 Stein, Switzerland GLP, not published Syngenta File No CGA62826/0008 (VV-372576)	Y	N	Expired on 10/1/2012	SYN	-
KCA 5.8.1	Winkler, G	1996	CGA62826 Acute Dermal Toxicity in the rat (limit test) 963101 Ciba-Geigy Ltd., 4332 Stein, Switzerland GLP, not published Syngenta File No CGA62826/0007 (VV-353936)	Y	N	Expired on 10/1/2012	SYN	-
KCA 5.8.1	Fankhauser, H	1997	28-Days subacute, oral toxicity study in rats (gavage). [CGA62826] Novartis Crop Protection AG, CH-4332 Stein, Switzerland GLP, not published Syngenta File No CGA62826/0011 (VV-353945)	Y	N	Expired on 10/1/2012	SYN	-
KCA 5.8.1	Ogorek, B	1997	Samonella and escherichia/mammalian microsome mutagenicity test, CGA 108906, metabolite of CGA 48988. 963127 Novartis Crop Protection, Basel, Switzerland GLP Unpublished Syngenta File No (VV-353948)	N	N	Expired on 10/1/2012	SYN	-

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KCA 5.8.1	Hartmann H	1994	Acute Oral Toxicity in the Rat 943085 Short-term toxicology, Ciba-Geigy Ltd, 4332, Stein, Switzerland GLP Unpublished	Y	N	Expired on 10/1/2012	SYN	-
KCA 5.8.1	Winkler G	1996	Acute dermal toxicity in the rat (limit test) CGA 108906, metabolite of CGA 48988. 963126 Ciba-Geigy Ltd., Stein, Switzerland GLP Unpublished	Y	N	Expired on 10/1/2012	SYN	-
KCA 5.8.1	Gerspach R	1997	28 day Subacute, Oral toxicity study in rats (gavage) 963128 Novartis Crop Protection AG, 4332 Stein, Switzerland GLP Unpublished	Y	N	Expired on 10/1/2012	SYN	-
CA 5.8.2 KIIA 5.8	Demsia, G Vlastos, D, Goumenou, M, Demetrios P Matthopoulos, D.P.	2007	Assessment of the genotoxicity of imidacloprid and metalaxyl in cultured human lymphocytes and rat bone-marrow, Non-GLP, published Mutation Research 634 (2007) 32–39	N/A	N	N/A	SYN	-
CA 5.8.1 KIIA 5.8	Deparade, E	1998	Gene mutation test with Chinese hamster cells V79. CGA 108906 Novartis Crop Protection AG, Basel, Switzerland, 983071 GLP, not published Syngenta File No CGA108906/0009 (VV-308272)	N	Y	New study never submitted before to this country	SYN	-
CA 5.4.1 KIIA 5.4.2	Deparade, E	1999	CGA329351 tech. Micronucleus test, mouse. Report No. 993096, dated 27.10.1999 Novartis Crop Protection AG, Basel, Switzerland. GLP, not published Syngenta File No CGA329351/1173 (VV-309437)	Y	Y	New study never submitted before to this country	SYN	-

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CA 5.9 KIIA 5.9	De Schampheleir e M; Nuyttens D; De Keyser D; Spanoghe P	2009	Evaporation drift of pesticides active ingredients. Non-GLP, published Communications in agricultural and applied biological sciences, (2008) Vol. 73, No. 4, pp. 739-742.	N/A	N	N/A	SYN	-
CA 5.1 KIIA 5.1	Ding Fei; Li Xiu-Nan; Diao Jian-Xiong; Sun Ye; Zhang Li; Sun Ying	2012	Chiral recognition of metalaxyl enantiomers by human serum albumin: evidence from molecular modeling and photophysical approach. Non-GLP, published Chirality, (2012 Jun) Vol. 24, No. 6, pp. 471-80.	N/A	N	N/A	SYN	-
KIIA 5.9	Esteve-Turrillas FA, Pastor A, De La Guardia M	2009	Use of semipermeable membrane devices for monitoring pesticides in indoor air. Non-GLP, published Journal of J AOAC Int. 2009 Sep-Oct; 92(5):1557-65.	N/A	N	N/A	SYN	-
KIIA 5.6	Farag, A.T., Ebrahim H.H., Attia, A.A. and Kadous, E.A	2012	Assessment of Developmental Toxicity of Metalaxyl in Pregnant Mice Non-GLP, published J Environ Anal Toxicol 2012, 2, 6, 1-7 www.omicsonline.org/2161-0525/2161-0525-2-153.pdf [study not accepted - unreliable]	N/A	N	N/A	SYN	-
KIIA 5.8.1	Gan, J, Skipper PL, Gago-Dominguez, M, Arakawa,K, Ross, RK, Yu, MC, Tannenbaum, SR	2004	Alkylaniline-Hemoglobin Adducts and Risk of Non-Smoking-Related Bladder Cancer,Non-GLP, published Journal of the National Cancer Institute, 96 (19), 2004	N/A	N	N/A	SYN	-

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KIIA 5.8.3	Goetz-Bouchard A.K., Biedler, T	2013	Workshop abstract - “Retrospective Analysis of Syngenta Compounds – Predictive Value of ToxCast™ High-Throughput Assays for Endocrine Disruptor Screening Tier I Studies” Workshop 23-24.04.2013, North Carolina Biotechnology Center, Research Triangle Park, North Carolina, USA Non-GLP, published	N/A	N	N/A	SYN	-
KIIA 5.8.3	Hoberman	2011	Oral (Gavage) Uterotrophic Bioassay of Metalaxyl in Female Rats. Charles River Laboratories Preclinical Services, Pennsylvania. Project No. 20012406. December 9, 2011. GLP, not published MRID: 48617606. Syngenta File No CGA048988_50041 (VV-506320)	Y	Y	New study never submitted before to this country	SYN	-
KIIA 5.8.1	Kirkland, D, Ballantyne, M, Harlfinger S, Will, O, Jahnel, U, Kraus, A, Van Dorp, C	2012	Further investigations into the genotoxicity of 2,6-xylydine and one of its key metabolites Non-GLP, published Regulatory Toxicology and Pharmacology, 62, 151-159, 2012.	N/A	N/A	-	SYN	-
KIIA 5.8.1	Kornreich and Montgomery	1990	TP technical report on the toxicology and carcinogenesis studies on 2,6-xylydine in Charles River CD rats (feed studies)(NTP TR 278, 06/1990) http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/tr278.pdf	N/A	N/A	-	SYN	-
KIIA 5.8.1	Ogorek, B	1998	Gene mutation test with Chinese hamster cells V79 Novartis Crop Protection AG, Basel, Switzerland, 983070, GLP, not published Syngenta File No CGA62826/0016 (VV-312522)	N	Y	New study never submitted before to this country	SYN	-

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KIIA 5.4.2	Ogorek, B.	2000	CGA 329351 tech. Autoradiographic DNA repair test on rat hepatocytes (OECD conform) in vitro. Report No. 993097, 10.03. 2000 Novartis Crop Protection AG, Basel, Switzerland. GLP, not published Syngenta File No CGA329351/1279 (VV-309826)	N	Y	New study never submitted before to this country	SYN	-
KIIA 5.8.1	Qiu Jing; Wang QiuXia; Wang Ping; Jia GuiFang; Li JunLing; Zhou ZhiQiang; Qiu, J.; Wang, Q. X.; Wang, P.; Jia, G. F.; Li, J. L.; Zhou, Z. Q.,	2005	Enantioselective degradation kinetics of metalaxyl in rabbits. Non-GLP, published Pesticide Biochemistry and Physiology (2005) Volume 83, N° 1, pp. 1-8	N/A	N/A	-	SYN	-
KIIA 5.6	Reddy, M. V. B.; Krishnamurthi, M. K.; Shetty, H. S	1990	Short term dietary toxicity of Apron 35 SD (metalaxyl) to albino rats Rattus norvegicus albinicus. Non-GLP, published Pesticide Research Journal (1990) Volume 2, Number 2, pp. 139-144	N/A	N/A	-	SYN	-
KIIA 5.3	Rao MV, Sunder RS and Chawla SL	2005	Reproductive toxicity of a fungicide combination. (Metalaxyl + Mancozeb) in adult rats Non-GLP, published J Cell Tissue Res 5, 299-302	N/A	N/A	-	SYN	-
KIIA 5.9	Sanjuan-Herraez, D; Rodriguez-Carrasco, Y; Juan-Peiro, L; Pastor, A; de la Guardia,	2011	Determination of indoor air quality of a phytosanitary plant Non-GLP, published Analytica Chimica Acta, (2011) Vol. 694, No. 1-2, pp. 67-74	N/A	N/A	-	SYN	-

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KIIA 5.3	Sato	1982	13 week subacute toxicity study of CGA 48 988 in rat, original report 02.03.1982, translation from Japanese original report, 01.2005; Syngenta Crop Protection AG, Basel, Switzerland Nippon Experimental Medical Research Institute Co. Ltd., Ohdo, Japan, GLP status uncertain, not published Syngenta File No CGA48988/5095 (VV-332387)	Y	N	-	SYN	-
KIIA 5.9	Schummer, C; Salquebre, G; Briand, O; Millet, M; Appenzeller, B M. R	2012	Determination of farm workers' exposure to pesticides by hair analysis Non-GLP, published Toxicology Letters (2012), 210 (2), pp.203-210	N/A	N/A	-	SYN	-
KIIA 5.1.3	Shaw, J, Montgomery, E	2011	Metalaxyl-M Tissue Distribution and Elimination in the Rat Following Repeated Daily Oral Administration of 2 mg [Phenyl-U-14C]-Metalaxyl-M/kg Syngenta Charles River Laboratories, Edinburgh, United Kingdom, 31644 GLP, not published Syngenta File No CGA329351_11470 (VV-397958)	Y	Y	New study never submitted before to this country	SYN	-
KIIA 5.8	Sokolowski, A	2012	CGA92370 - Salmonella typhimurium and Escherichia coli Reverse Mutation Assay Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1449001 GLP, not published Syngenta File No CGA092370_10002 (VV-402487)	N	Y	New study never submitted before to this country	SYN	-
KIIA 5.8.3	Wagner	2011	Metalaxyl: H295R Steroidogenesis Assay. CeeTox, Inc., Kalamazoo, MI. Study No. 9143V-100326STER. 07 December 2011. GLP, not published MRID 48617605. Syngenta File No CGA048988_50040 (VV-405641)	N	Y	New study never submitted before to this country	SYN	-

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KIIA 5.8.3	Wilga	2011	Metalaxyl: Human Recombinant Aromatase Assay. CeeTox, Inc., Kalamazoo, MI. Study No. 9143V-100326AROM. 07 December 2011. GLP, not published MRID 48617602. Syngenta File No CGA048988_50036 (VV-506315)	N	Y	New study never submitted before to this country	SYN	-
KIIA 5.8.3	Willoughby	2011a	Metalaxyl: Estrogen Receptor Binding (Rat Uterine Cytosol) CeeTox, Inc., Kalamazoo, MI. Study No. 9143V -100326ERB. 08 December 2011. GLP, not published MRID 4867607. Syngenta File No CGA048988_50037 (VV-405413)	N	Y	New study never submitted before to this country	SYN	-
KIIA 5.8.3	Willoughby	2011b	Metalaxyl: Estrogen Receptor Transcriptional Activation (Human Cell Line (Hela-9903)). CeeTox, Inc., Kalamazoo, MI. Study No. 9143V-100326ERTA. 07 December 2011. GLP, not published MRID 48617603. Syngenta File No CGA048988_50038 (VV-405414)	N	Y	New study never submitted before to this country	SYN	-
KIIA 5.8.3	Willoughby	2011c	Metalaxyl: Androgen Receptor Binding (Rat Prostate Cytosol). CeeTox, Inc., Kalamazoo, MI. Study No. 9143V-100326ARB. 07 December 2011. GLP, not published MRID 48617601. Syngenta File No CGA048988_50035 (VV-405411)	N	Y	New study never submitted before to this country	SYN	-
KIIA 5.6.2	Winkler, G	1996d	Acute oral toxicity in the mouse, Test n° 963013, CGA 329351 tech. Testing facility: Short-term Toxicology, Ciba-Geigy Limited, 4332 Stein / Switzerland. Sponsor: Ciba-Geigy Ltd, Crop Protection Division, 4002 Basel/Switzerland. Study issued March 20, 1996 GLP, not published Syngenta File No CGA329351/0372 (VV-372573)	Y	Y	New study never submitted before to this country	SYN	-

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KIIA 5.8	Wollny, H	2012	CGA92370 - Cell Mutation Assay at the Thymidine Kinase Locus (TK +/-) in Mouse Lymphoma L5178Y Cells Syngenta Harlan Cytotest Cell Research GmbH (Harlan CCR), Germany, 1449003 GLP, not published Syngenta File No CGA092370_10004 (VV-402489)	N	Y	New study never submitted before to this country	SYN	-
CA 6.0 KIIA 6.1.1 / 01	Kühne R.	2003	Stability of Residues of Metalaxyl-M (CGA 329351) in Deep Freeze Stored Analytical Specimens of Oranges (fruit), Potatoes (tuber), Rape Seed (seed), Tomatoes (fruit) and Wheat (grain) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 201/01 GLP, not published Syngenta File No CGA329351/1737 (VV-329090)	N	Y	New study never submitted before to this country	SYN	-
CA 6.0 KIIA 6.1.1 / 02	Grunenwald M.	1999	Stability of CGA 329351, CGA 62826 and CGA 94689 in Crops and Processed Fractions under Freezer Storage Conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Inc., Greensboro, USA, 119-96 GLP, not published Syngenta File No CGA329351/1159 (VV-312754)	N	Y	Data protection started with 3659 on 13.10.2015; Expiry date 13.10.2025	SYN	-
CA 6.0 KIIA 6.1.1 / 03	Grunenwald M.C.	1998	Stability of CGA-329351, CGA 62826, and CGA-94689 in Meat, Milk, and Eggs, Under Freezer Storage Conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Inc., Greensboro, USA, ABR-98053 GLP, not published Syngenta File No CGA329351/1006 (VV-376022)	N	Y	New study never submitted before to this country	SYN	-
CA 6.1 [Previously evaluated in DAR addendum May 2000]	Stingelin, J.	2000	Comparative Metabolism of phenyl-(U)-14C CGA 329351 and phenyl-(U)-14C CGA 48988 in Field Grown Lettuce. Novartis Crop Protection AG, Basel, Switzerland Report No. 98JS30, January 25, 2000 GLP, not published Novartis File N° 329351/1254 Syngenta File No CGA329351/1254 (VV-312114)	N	N	Expired on 10/1/2012	SYN	-

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CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Gross, D	1977	Metabolism of CGA 48988 in field grown potato plants, Ciba-Geigy Ltd., Basle. Rep.Nr. 30-77, 31.05.1977 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2022 Syngenta File No CGA48988/2022 (VV-361940)	N	N	Expired on 10/1/2012	SYN	-
CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Gross, D	1978	Metabolism of CGA 48988 in grapevine, Ciba-Geigy Ltd., Basle. Rep.Nr. 11-78, 20.02.1978 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2017 Syngenta File No CGA48988/2017 (VV-362221)	N	N	Expired on 10/1/2012	SYN	-
CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Gross, D	1979a	Fate of CGA 48988 in lettuce, Ciba-Geigy Ltd., Basle. Rep.Nr. 39-79, 05.10.1979 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2019 Syngenta File No CGA48988/2019 (VV-361173)	N	N	Expired on 10/1/2012	SYN	-
CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Gross, D	1979b	Identificarion of metabolites of CGA 48988 in grapevine, Ciba-Geigy Ltd., Basle. Rep.Nr. 06-79, 08.03.1979 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2018 Syngenta File No CGA48988/2018 (VV-362229)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Gross, D	1979c	Identification of metabolism of CGA 48988 in field grown potatoes, Ciba-Geigy Ltd., Basle. Rep.Nr. 39-79, 30.10.1979 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2025 Syngenta File No CGA48988/2025 (VV-361933)	N	N	Expired on 10/1/2012	SYN	-
CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Gross, D	1980	Identification of degradation products of CGA 48988 in lettuce, Ciba-Geigy Ltd., Basle. Rep.Nr. 38-80, 05.10.1980 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2020 Syngenta File No CGA48988/2020 (VV-362234)	N	N	Expired on 10/1/2012	SYN	-
CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Honeycutt, R.C; Fischer, W.C; Cassidy, J.E	1979d	Uptake and balance of 0-14C-CGA 48988 and its metabolites in field grown bright tobacco, Ciba-Geigy Corp, Greensboro NC, USA. Rep.Nr. ABR-79100, 10.10.1979 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2031 Syngenta File No CGA48988/2031 (VV-361927)	N	N	Expired on 10/1/2012	SYN	-
CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Honeycutt, R.C; Fischer, W.C; Madrid, S; Cassidy, J.E	1981	Uptake, balance and metabolism of 0-14C-CGA 48988 in field grown potatoes, Ciba-Geigy Corp, Greensboro NC, USA. Rep.Nr. ABR-81037, 17.09.1981 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2026 Syngenta File No CGA48988/2026 (VV-378158)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Honeycutt, R.C; Simoneaux, B.J; Szolics, I.M; Cassidy, J.C	1978c	Charakterization of polar metabolites of 0-14C-CGA 48988 in greenhouse grown bright tobacco, Ciba-Geigy Corp, Greensboro NC, USA. Rep.Nr. ABR-78044, 22.05.1978 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2029 Syngenta File No CGA48988/2029 (VV-362241)	N	N	Expired on 10/1/2012	SYN	-
CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Honeycutt, R.C; Simoneaux, B.J; Szolics, I.M; Cassidy, J.C	1979b	Identification of the major aglycones of 0-14C-CGA 48988 conjugated metabolites in cured greenhouse grown bright tobacco, Ciba-Geigy Corp, Greensboro NC, USA. Rep.Nr. ABR-79008, 25.04.1979 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2030 Syngenta File No CGA48988/2030 (VV-361922)	N	N	Expired on 10/1/2012	SYN	-
CA 6.1 [Previously evaluated in DAR July 1999; Supplementary info for renewal]	Seim, V and Honeycutt, R.C; Cassidy, J.C	1978	Uptake, balance and metabolism of 0-14C-CGA 48988 and its metabolites in greenhouse grown bright and burley tobacco, Ciba-Geigy Ltd., Basle. Rep.Nr. ABR-78036, 24.04.1978 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/2028 Syngenta File No CGA48988/2028 (VV-362165)	N	N	Expired on 10/1/2012	SYN	-
CA 6.1 KIIA 6.2.1 / 01	Stingelin J.	2003	Metabolism of [Phenyl-(U)-14C] CGA 329351 after Seed Treatment in Field Grown Spring Wheat Syngenta Crop Protection AG, Basel, Switzerland Syngenta AG, Basel, Switzerland, 02JS38 GLP, not published Syngenta File No CGA329351/1802 (VV-378934)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.1	Stingelin J.	2003	Metabolism of [phenyl-(U)-14C] CGA 48988 after seed treatment in field grown spring wheat. Syngenta Crop Protection AG, Basel, Switzerland Syngenta AG, Basel, Switzerland, Report No 02JS37 GLP, not published Syngenta File No CGA48988/5038 (VV-340045)	N	Y	New study never submitted before to this country	SYN	-
CA 6.1 KIIA 6.2.1 / 02	Miner P.	2012	14C_Metalaxyl-M: Metabolism in tomatoes. Syngenta Crop Protection AG, Basel, Switzerland Ricerca Biosciences LLC., Concord, USA. 026135-1 GLP, not published Syngenta File No CGA329351_50842 (VV-402254)	N	Y	New study never submitted before to this country	SYN	-
CA 6.2 KIIA 6.2.2 / 01 [Previously evaluated in DAR July 1999]	Kennedy E.	1990	Metabolism of [Φ-14C]-metalaxyl in hens Ciba-Geigy Corp., Greensboro, USA Ciba-Geigy Corp., Greensboro, USA, ABR-90077 GLP, not published Syngenta File No CGA48988/2896 (VV-373685)	N	N	Expired on 10/1/2012	SYN	-
CA 6.2 KIIA 6.2.2 / 02	Seim, V., Pickles.	1990	Biological report for the metabolism of 14C-metalaxyl in laying hens. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, USA, BIOL-89005 GLP, not published Syngenta File No CGA48988/0579 (VV-346587)	N	Y	New study never submitted before to this country	SYN	-
CA 6.2 KIIA 6.2.2 / 03 [Previously evaluated in DAR July 1999]	Kennedy E.	1991	Supplemental report on the metabolism of [Φ-14C]-metalaxyl in hens Ciba-Geigy Corp., Greensboro, USA Ciba-Geigy Corp., Greensboro, USA, ABR-91077 GLP, not published Syngenta File No CGA48988/3205 (VV-25432)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.2 KIIA 6.2.2 / 04	Seim, V., Pickles.	1991	Biological report for the metabolism of [Φ-14C]-metaxyl in chickens. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, USA, BIOL-91011 GLP, not published Syngenta File No CGA48988/3206 (VV-373595)	N	Y	New study never submitted before to this country	SYN	-
CA 6.2 KIIA 6.2.3 / 01 [Supplementary info for renewal]	Fischer W.C., Foster, R.A., Cassidy, J.E.	1978	Balance and metabolism of Φ-14C-CGA 48988 in a lactating goat. Ciba-Geigy Corp., Greensboro, USA Ciba-Geigy Corp., Greensboro, USA, ABR-78046 Not GLP, not published Syngenta File No CGA48988/0575 (VV-346596)	N	N	Expired on 10/1/2012	SYN	-
CA 6.2 KIIA 6.2.3 / 02 [Supplementary info for renewal]	Seim, V.	1978	Biological report for the metabolism of [phenyl]14C-CGA-48988 in a lactating goat Ciba-Geigy Corp., Greensboro, USA Ciba-Geigy Corporation, Greensboro, USA. BIOL-78002 Not GLP, not published Syngenta file no. CGA048988_11208 (VV-402321)	N	N	Expired on 10/1/2012	SYN	-
CA 6.2 KIIA 6.2.3 / 03 [Previously evaluated in DAR July 1999]	Emrani J.	1990	Metabolism of [Φ-14C]-metaxyl in goats Ciba-Geigy Corp., Greensboro, USA Ciba-Geigy Corp., Greensboro, USA, ABR-90078 GLP, not published Syngenta File No CGA48988/2897 (VV-373471)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.2 KIIA 6.2.3 / 04 [Previously evaluated in DAR July 1999]	Emrani J.	1991	Supplemental report on the metabolism of [Φ -14C]-metalaxyl in goats. Ciba-Geigy Corp., Greensboro, USA Ciba-Geigy Corp., Greensboro, USA, ABR-91075 GLP, not published Syngenta File No CGA48988/3208 (VV-25433)	N	N	Expired on 10/1/2012	SYN	-
CA 6.2 KIIA 6.2.3 / 05	Seim, V., Pickles.	1990a	Biological report for the metabolism of 0-14C-metalaxyl in a lactating goat Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, USA, BIOL-89010 GLP, not published Syngenta File No CGA48988/0576 (VV-346585)	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 [submitted as additional information during AIR peer review]	Goellner C., Klimmek S.	2014	Metalaxyl-M – Analytical Method GRM031.07A for the Determination of the Metalaxyl-M Metabolites CGA62826 and CGA94689 in Crop Matrices. Analytical method.Eurofins Agrosience Services Chem GmbH, Report No. GRM031.07A; Syngenta File No. CGA062826_10005 (VV-128254) GLP not applicable Unpublished	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 [submitted as additional information during AIR peer review]	Klimmek S., Gisler A, Goellner C.	2014	Metalaxyl-M – Analytical Method GRM031.07A for the Determination of the Metalaxyl-M Metabolites CGA62826 and CGA94689 in Crop Matrices. Method Validation. Eurofins Agrosience Services Chem GmbH, Report No. S11-03384; Syngenta File No. CGA062826_10003 (VV-128249) GLP Unpublished	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.3 [submitted as additional information during AIR peer review]	Klimmek S., Gisler A.	2014	CGA62826 and CGA94689 - Residue Analysis of CGA62826 and CGA94689 in Samples of Tomato from Studies S11-01399 and S11-01400 and Grapes from Studies S11-01401 and S11-01402. Eurofins Agrosience Services Chem GmbH, Report No. S11-03825; Syngenta File No. CGA062826_10004 (VV-406720) GLP Unpublished	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 [Previously evaluated in DAR July 1999]	Kühne, R.O,	1995g	CGA 329351 + Copper, WP 42.5, Grapes (berries), Italy, Ciba-Geigy Ltd., Basle, Switzerland August 10, 1995, Project Report 2124/94 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited329351/ 143 Syngenta File No CGA329351/0143 (VV-369706)	N	N	Expired on 10/1/2012	SYN	-
CA 6.3 [Previously evaluated in DAR July 1999]	Kühne, R.O,	1995l	CGA 329351 + Folpet, WP 45, Grapes (berries), Italy, Ciba-Geigy Ltd., Basle, Switzerland August 9, 1995, Project Report 2122/94 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited329351/ 141 Syngenta File No CGA329351/0141 (VV-353585)	N	N	Expired on 10/1/2012	SYN	-
CA 6.3 KIIA 6.3.1 / 01	Zell M., Breyer N.	2011	Metalaxyl-M and Mancozeb - Residue Study on Wine Grapes in Northern France in 2010 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S10-01307 GLP, not published Syngenta File No A9651D_10080 (VV-400842)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.3 KIIA 6.3.1 / 02	Zell M., Breyer N.	2011a	Metalaxyl-M and Mancozeb - Residue Study on Wine Grapes in Northern France in 2010 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S10-01310 GLP, not published Syngenta File No A9651D_10081 (VV-400845)	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 KIIA 6.3.1 / 03	Zell M.	2011	Metalaxyl-M and Copper - Residue Study on Wine Grapes in Southern France, Italy and Spain in 2010 Syngenta Eurofins - Dr Specht & Partner, Hamburg, Germany, S10-01321 GLP, not published Syngenta File No A15605C_11178 (VV-397621)	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 KIIA 6.3.1 / 04	Zell M., Breyer N.	2011b	Metalaxyl-M and Mancozeb - Residue Study on Wine Grapes in Southern France, Spain and Greece in 2010 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S10-01308 GLP, not published Syngenta File No A9651D_10082 (VV-400866)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.3 KIIA 6.3.1 / 05	Zell M., Breyer N.	2011c	Metalaxyl-M and Mancozeb - Residue Study on Wine Grapes in Southern France in 2010 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S10-01309 GLP, not published Syngenta File No A9651D_10079 (VV-400751)	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 KIIA 6.3.1 / 06	Klimmek S., Zell M., Amann S.	2012	Metalaxyl-M and Mancozeb - Residue Study on Wine Grapes in Southern France and Italy in 2011 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S11-01402 GLP, not published Syngenta File No A9651D_10093 (VV-401143)	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 KIIA 6.3.1 / 07	Klimmek S., Zell M., Amann S.	2012a	Metalaxyl-M and Mancozeb - Residue Study on Wine Grapes in Northern France and Germany in 2011 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S11-01401 GLP, not published Syngenta File No A9651D_10096 (VV-401668)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.3 KIIA 6.3.2 / 01	Kuhne R.O.	1999	Residue Study with Mancozeb (ASF 21) and Metalaxyl-M (CGA 329351) in or on Tomatoes in Switzerland Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2073/98 GLP, not published Syngenta File No CGA329351/1145 (VV-309063)	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 KIIA 6.3.2 / 02 [Previously evaluated in DAR July 1999]	Kuhne R.O.	1998	Residue Study with Metalaxyl-M (CGA 329351) and Mancozeb (ASF 21) in or on Tomatoes in Switzerland Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2334/97 GLP, not published Syngenta File No CGA329351/0926 (VV-377436)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.3 KIIA 6.3.2 / 03 [Previously evaluated in DAR July 1999]	Kuhne R.O.	1998a	Residue Study with Metalaxyl-M (CGA 329351) and Copper as Copper Oxichloride (ASF 45) in or on Tomatoes in Switzerland Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2335/97 GLP, not published Syngenta File No CGA329351/0928 (VV-377437)	N	N	Expired on 10/1/2012	SYN	-
CA 6.3 KIIA 6.3.2 / 04 [Previously evaluated in DAR July 1999]	Kuhne R.O.	1998b	Residue Study with Metalaxyl-M (CGA 329351) and Mancozeb (ASF 21) in or on Tomatoes in Switzerland Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2336/97 GLP, not published Syngenta File No CGA329351/0927 (VV-377439)	N	N	Expired on 10/1/2012	SYN	-
KIIA 6.3.2 / 05 [Previously evaluated in DAR July 1999]	Kuhne R.O.	1998c	Residue Study with Metalaxyl-M (CGA 329351) and Copper as Copper Oxichloride (ASF 45) in or on Tomatoes in Switzerland Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2337/97 GLP, not published Syngenta File No CGA329351/0929 (VV-377442)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.3 KIIA 6.3.2 / 06	Zell M., Amann S., Breyer N.	2012	Metalaxyl-M and Mancozeb - Residue Study on Field Tomatoes in Northern Europe in 2010 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S10-01299 GLP, not published Syngenta File No A9651D_10083 (VV-401037)	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 KIIA 6.3.2 / 07	Klimmek S., Zell M., Amann S.	2012b	Metalaxyl-M and Mancozeb - Residue Study on Field Tomatoes in Northern France in 2011 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S11-01399 GLP, not published Syngenta File No A9651D_10097 (VV-401679)	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 KIIA 6.3.2 / 08	Oliver-Kang J	2008	Metalaxyl-M (CGA329351): Residue Study on Field Tomatoes in Spain and Italy in 2007 Syngenta - Jealott's Hill, Bracknell, United Kingdom CEMAS, North Ascot, United Kingdom, CEMR-3388-REG, T011077-06 GLP, not published Syngenta File No CGA329351_10766 (VV-382220)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.3 KIIA 6.3.2 / 09	Zell M., Amann S., Breyer N.	2012a	Metalaxyl-M and Mancozeb - Residue Study on Field Tomatoes in Southern Europe in 2010 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S10-01300 GLP, not published Syngenta File No A9651D_10084 (VV-400992)	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 KIIA 6.3.2 / 10	Klimmek S., Zell M., Amann S.	2012c	Metalaxyl-M and Mancozeb - Residue Study on Field Tomatoes in Italy and Spain in 2011 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S11-01400 GLP, not published Syngenta File No A9651D_10098 (VV-401689)	N	Y	New study never submitted before to this country	SYN	-
CA 6.3 KIIA 6.3.3 / 01 [Previously relied upon in Review report Sept. 2002]	Kuhne R.O.	1998d	CGA 329351, ES 350, A-9642 C, Spinach, The Netherlands Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 142/97 GLP, not published Syngenta File No CGA329351/0794 (VV-357037)	N	N	Expired on 10/1/2012	SYN	-
CA 6.3 KIIA 6.3.3 / 06 [Previously relied upon in Review report Sept. 2002]	Kuhne R.O.	1998f	CGA 329351, ES 350, A-9642 C, Spinach, Italy Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 155/97 GLP, not published Syngenta File No CGA329351/0937 (VV-357464)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.3 KIIA 6.3.4 / 01 [Previously relied upon in Review report Sept. 2002]	Kuhne R.O.	1999d	Residue Study with Metalaxyl-M (CGA 329351) in or on Sunflowers in France (North) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2118/98 GLP, not published Syngenta File No CGA329351/1079 (VV-308789)	N	N	Expired on 10/1/2012	SYN	-
CA 6.3 KIIA 6.3.4 / 02 [Previously relied upon in Review report Sept. 2002]	Kuhne R.O.	1999e	Residue Study with Metalaxyl-M (CGA 329351) in or on Sunflowers in France (North) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2119/98 GLP, not published Syngenta File No CGA329351/1080 (VV-308790)	N	N	Expired on 10/1/2012	SYN	-
CA 6.3 KIIA 6.3.4 / 03	Kuhne R.O.	2001	Residue Study with Metalaxyl-M (CGA 329351) in or on Sunflowers in France (North) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 4013/99 GLP, not published Syngenta File No CGA329351/1447 (VV-310977)	N	Y	Data protection started with 3979 on 30.11.2018; Expiry date 30.11.2028	SYN	-
CA 6.3 KIIA 6.3.4 / 04	Kuhne R.O.	2001a	Residue Study with Metalaxyl-M (CGA 329351) in or on Sunflowers in France (North) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 4014/99 GLP, not published Syngenta File No CGA329351/1448 (VV-310978)	N	Y	Data protection started with 3979 on 30.11.2018; Expiry date 30.11.2028	SYN	-
CA 6.3 KIIA 6.3.4 / 05 [Previously relied upon in Review report Sept. 2002]	Kuhne R.O.	1999f	Residue Study with Metalaxyl-M (CGA 329351) in or on Sunflowers in France (South) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2120/98 GLP, not published Syngenta File No CGA329351/1081 (VV-308791)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.3 KIIA 6.3.4 / 06 [Previously relied upon in Review report Sept. 2002]	Kuhne R.O.	1999g	Residue Study with Metalaxyl-M (CGA 329351) in or on Sunflowers in France (South) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2121/98 GLP, not published Syngenta File No CGA329351/1082	N	N	Expired on 10/1/2012	SYN	-
CA 6.3 KIIA 6.3.4 / 07 [Previously relied upon in Review report Sept. 2002]	Kuhne R.O.	1999h	Residue Study with Metalaxyl-M (CGA 329351) in or on Sunflowers in Spain Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2116/98 GLP, not published Syngenta File No CGA329351/1161 (VV-309374)	N	N	Expired on 10/1/2012	SYN	-
CA 6.3 KIIA 6.3.4 / 08	Kuhne R.O.	2000	Residue study with metalaxyl-M (CGA 329351) in or on sunflowers in Spain Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 4012/99 GLP, not published Syngenta File No CGA329351/1344 (VV-378733)	N	Y	Data protection started with 3979 on 30.11.2018; Expiry date 30.11.2028	SYN	-
CA 6.4 [Previously evaluated in DAR July 1999]	Eudy, L.W	1991	CGA 48988 - Three level 28 day poultry study, Ciba-Geigy Corp., Greensboro NC, USA, Rep.Nr. ABR-91047, 25.11.1991 Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited 48988/3164 Syngenta File No CGA48988/3167 (VV-373475)	N	N	Expired on 10/1/2012	SYN	-
CA 6.4 KIIA 6.4.1 / 01	Seim V.W., Thomas W.A.	1980	Biological report for CGA-48988 residue test in laying hens. Ciba-Geigy Corporation, Vero Beach, USA. BIOL-80009 Not GLP, not published Syngenta File No. CGA048988_11209 (VV-402322)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.4 KIIA 6.4.1 / 02	Seim V.	1980	CGA 48988, chickens, USA Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, USA, AG-A-5998-I-II Not GLP (not yet required), not published Syngenta File No CGA48988/1976 (VV-112730)	N	N	N/A	SYN	-
CA 6.4 KIIA 6.4.1 / 03	Cheung M.W.	1980	CGA 48988, Poultry feed, USA Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, USA, AG-A-6149-I-II Not GLP (not yet required), not published Syngenta File No CGA48988/3811 (VV-115438)	N	N	N/A	SYN	-
CA 6.4 [Previously evaluated in DAR July 1999]	Kahrs, R.A	1982a	Residues of CGA 48988 and metabolites in tissues and milk of dairy cows receiving CGA 48988 in their diet, Ciba-Geigy Corp., USA, Rep.Nr. ABR-82052, 31.08.1982 Not GLP Owner: Ciba-Geigy Limited Submitted by: Ciba-Geigy Limited48988/1982 Syngenta File No CGA48988/1982 (VV-346597)	N	N	Expired on 10/1/2012	SYN	-
CA 6.4 KIIA 6.4.2 / 01	Seim V., Thomas W., Brown G.	1980	Biological report for CGA-48988 residue test in lactating cows. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corporation, Vero Beach, USA. BIOL-79009 Not GLP, not published Syngenta File No.CGA048988_11210 (VV-402323)	N	N	N/A	SYN	-
CA 6.4 KIIA 6.4.2 / 02	Seim V.	1980a	CGA 48988 technical, milk, USA Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, USA, AG-A-5716-I-III-V-VI-VII Not GLP (not yet required), not published Syngenta File No CGA48988/1985 (VV-112728)	N	N	N/A	SYN	-
CA 6.4 KIIA 6.4.2 / 03	Seim V.	1980b	CGA 48988, technical, cows, USA Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, USA, AG-A-5716-IV-V-VI-VII/-2 Not GLP (not yet required), not published Syngenta File No CGA48988/1977 (VV-112731)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.4 KIIA 6.4.2 / 04	Seim V.	1981	CGA 48988, technical, cows, USA Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Corp., Greensboro, USA, AG-A-5716-IV-V-VI-VII/-3 Not GLP (not yet required), not published Syngenta File No CGA48988/1978 (VV-112815)	N	N	N/A	SYN	-
CA 6.5.1 [Previously evaluated in DAR addendum Sept 2001]	Adam, D.	2000	Hydrolysis of 14C-labelled CGA 329351 under processing conditions NovartisCrop Protection AG, 19 July 2000 Report N° 00DA05 GLP, not published Novartis file N° : CGA329351/1386 (VV-312115)	N	N	Expired on 10/1/2012	SYN	-
CA 6.5.2 KIIA 6.5.4 / 01	Anderson L.	2005	Metalaxyl-M (CGA329351) and Chlorothalonil (R44686): Residue Study in or on Tomato and Processed Products in Spain Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, 04-6048 GLP, not published Syngenta File No CGA329351/2148 (VV-333947)	N	Y	New study never submitted before to this country	SYN	-
CA 6.5.2 KIIA 6.5.4 / 02	Klimmek S., Breyer N.	2012	Metalaxyl-M - Residue Study on Wine Grapes and Processed Specimens in Southern Europe in 2010 Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S10-01347 GLP, not published Syngenta File No A9651D_10111 (VV-402460)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.6 KIIA 6.6.2 / 08 [Previously evaluated in DAR July 1999]	McFarland J.	1992	Uptake and metabolism of metalaxyl in greenhouse rotational crops following target tobacco grown in soil treated with phenyl-14C-metalaxyl Ciba-Geigy Corp., Greensboro, USA Ciba-Geigy Corp., Greensboro, USA, ABR-91084 GLP, not published Syngenta File No CGA48988/3220 (VV-373666)	N	N	Expired on 10/1/2012	SYN	-
KIIA 6.6.2 / 09	Simoneaux B.	1994	Final report amendment on the uptake and metabolism of metalaxyl in greenhouse rotational crops following target tobacco grown in soil treated with [phenyl-14C]-metalaxyl (Amendment 1) Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy YCorp., Greensboro, USA, ABR-91084 A1 GLP, not published Syngenta File No CGA48988/3599 (VV-372115)	N	Y	New study never submitted before to this country	SYN	-
KIIA 6.6.2	Miner P.	2013	14C-Metalaxyl-M: Uptake and Metabolism in Confined Rotational Crops Ricerca Biosciences, LLC, 7528 Auburn Road, Concord, OH 44077 USA. Report No 026134-1 GLP, not published Syngenta File No CGA329351_50936 (VV-405070)	N	Y	New study never submitted before to this country	SYN	-
CA 6.6 KIIA 6.6.3 / 01 [Previously evaluated in DAR addendum May 2000]	Kuhne R.O.	2000a	Crop Rotation Study for Metalaxyl-M (CGA 329351) in follow-up Crop after Treatment of Potatoes in Switzerland Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 208/98 GLP, not published Syngenta File No CGA329351/1300 (VV-312676)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CA 6.6 KIIA 6.6.3 / 02 [Previously evaluated in DAR addendum May 2000]	Kuhne R.O.	2000b	Crop Rotation Study for Metalaxyl-M (CGA 329351) in follow-up Crop after Treatment of Potatoes in the United Kingdom Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 209/98 GLP, not published Syngenta File No CGA329351/1301 (VV-312675)	N	N	Expired on 10/1/2012	SYN	-
CA 6.6 KIIA 6.6.3 / 03 [Previously evaluated in DAR addendum May 2000]	Kuhne R.O.	2000c	Crop Rotation Study for Metalaxyl-M (CGA 329351) in follow-up Crop after Treatment of Potatoes in Italy Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 210/98 GLP, not published Syngenta File No CGA329351/1302 (VV-312674)	N	N	Expired on 10/1/2012	SYN	-
CA 6.6 KIIA 6.6.3 / 04	Klimmek S., Amann S.	2012	Metalaxyl-M - Residue Study on Rotational Crops in Germany and the United Kingdom in 2011 and 2012 Syngenta Eurofins Agroscience Services Chem GmbH, Hamburg, Germany, S11-00510 GLP, not published Syngenta File No A13947A_11113 (VV-117125)	N	Y	New study never submitted before to this country	SYN	-
CA 6.6 KIIA 6.6.3 / 05	Klimmek S., Amann S.	2012a	Metalaxyl-M - Residue Study on Rotational Crops in Southern France and Spain in 2011 and 2012 Syngenta Eurofins Agroscience Services Chem GmbH, Hamburg, Germany, S11-00511 GLP, not published Syngenta File No A13947A_11116 (VV-117126)	N	Y	New study never submitted before to this country	SYN	-

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IIA 7.1.1.1.1 CA 7.1.1.1.1	Dorn, R.;	2001a	Degradation of CGA 48988 in Soil "Birkenheide" Syngenta Crop Protection AG, Basel, Switzerland SLFA, Staat. Lehr-u.Forschungsanst.für Landwirtschaft, Neustadt, Germany, Report No NOV11 GLP Not Published Syngenta File N° CGA48988/5019 (VV-311553)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Dorn R., Hein W.	2003a	Degradation of CGA329351 in Soil "Birkenheide" Syngenta Crop Protection AG, Basel, Switzerland SLFA - Neustadt, Neustadt, Germany, NOV07 GLP, not published Syngenta File No CGA329351/1744 (VV-378541)	N	Y	Data protection started with 2180766 on 18.12.2019; Expiry date 18.12.2029	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Dorn, R.; Hein, W.;	2003b	Degradation of CGA351920 in Soil "Birkenheide" Syngenta Crop Protection AG, Basel, Switzerland SLFA - Neustadt, Neustadt, Germany, Report No NOV09 GLP Not Published Syngenta File N° CGA351920/0001 (VV-340167)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Dorn, R; Hein, W.;	2003c	Degradation of NOA409045 in Soil "Birkenheide" Syngenta Crop Protection AG, Basel, Switzerland SLFA - Neustadt, Neustadt, Germany, Report No NOV10 GLP Not Published Syngenta File N° NOA409045/0013 (VV-335927)	N	Y	New study never submitted before to this country	SYN	-

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IIA 7.1.1.1.1 CA 7.1.1.1.1	Dorn, R.; Hein, W.;	2003d	Degradation of NOA436575 in soil "Birkenheide" Syngenta Crop Protection AG, Basel, Switzerland SLFA - Neustadt, Neustadt, Germany, Report No NOV14 GLP Not Published Syngenta File N° NOA436575/0001 (VV-340166)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Dorn, R.; Hein, W.;	2003e	Degradation of CGA62826 in Soil "Birkenheide" Syngenta Crop Protection AG, Basel, Switzerland SLFA - Neustadt, Neustadt, Germany, Report No NOV06 GLP Not Published Syngenta File N° CGA62826/0023 (VV-378584)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Dorn, R; Möndel, M;	2003a	Degradation of CGA329351 in Soil "Pappelacker" Syngenta Crop Protection AG, Basel, Switzerland Dienstleistungszentrum Ländlicher Raum DLR, Neustadt, Germany, Report No SYN04 GLP Not Published Syngenta File N° CGA329351/1835 (VV-340375)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Dorn, R; Möndel, M;	2003b	Degradation of CGA351920 in Soil "Pappelacker" Syngenta Crop Protection AG, Basel, Switzerland Dienstleistungszentrum Ländlicher Raum DLR, Neustadt, Germany, Report No SYN05 GLP Not Published Syngenta File N° CGA351920/0002 (VV-340376)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.1.1.1 CA 7.1.1.1.1	Dorn, R; Möndel, M;	2003c	Degradation of CGA48988 in Soil "Pappelacker" Syngenta Crop Protection AG, Basel, Switzerland Dienstleistungszentrum Ländlicher Raum DLR, Neustadt, Germany, Report No SYN03 GLP Not Published Syngenta File N° CGA48988/5086 (VV-340374)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Ellgehausen, H.	1978	Degradation of CGA 48988 (Ridomil) in soil under aerobic, aerobic/anaerobic and sterile/aerobic conditions, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 08/78, 14.02.1978 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA48988/0193 (VV-377994)	N	N	N/A	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Ellgehausen, H.	1996a.	Metabolism of 14C-CGA 329351 under aerobic conditions in two soils at 20°C. Ciba-Geigy Ltd., Basle, Project No 95EH06 Owned by Ciba-Geigy Ltd., Basle, Switzerland, 24. September 1996 Submitted by Ciba-Geigy Ltd., Basel, Switzerland IR 95EH06 GLP Unpublished Syngenta File No CGA329351/0326 (VV-377872)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Guth, J.A.	1985a.	Degradation of metalaxyl (CGA 48988) in aerobic soils at a temperature of 15°C, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 19/85, 26.07.1985 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA48988/0197 (VV-347072)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.1.1.1 CA 7.1.1.1.1	Miner P., Hamilton L.	2012	CGA067868 - Rate of Aerobic Degradation of [14C]-CGA067868 in Three Soils Syngenta Ricerca Biosciences, LLC, Concord, OH, USA, 028585-1 GLP, not published Syngenta File No CGA092370_50001 (VV-402405)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Miner P., Herczog K.	2012a	[14C]-Metalaxyl-M - Rate and Route of Degradation under Aerobic Laboratory Conditions in Multiple Soils Syngenta Ricerca Biosciences, LLC, Concord, OH, USA, 026136-1 GLP, not published Syngenta File No CGA329351_50817 (VV-401719)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Miner P., Herczog K.	2012b	SYN546520 - Rate of Aerobic Degradation of [14C]-SYN546520 in Three Soils Syngenta Ricerca Biosciences, LLC, Concord, OH, USA, 027849-1 GLP, not published Syngenta File No SYN546520_50000 (VV-401720)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Schanne, C.	1991	Degradation of 14C-labelled metalaxyl in one soil incubated under various experimental conditions, RCC AG, Itingen, Switzerland, Rep.Nr. 262315, 16.12.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA48988/3091 (VV-373798)	N	N	Expired on 10/1/2012	SYN	-
IIA 7.1.1.1.1 CA 7.1.1.1.1	Suter, P.	1982	Degradation of CGA 62826 (metabolite of CGA 48988) in soil under aerobic conditions, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 35/82, 26.08.1982 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA48988/0195 (VV-346876)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.1.1.2 CA 7.1.1.1.2	Sparrow, K.	1995	Photodegradation of 14C-CGA329351 on soil under artificial light, Report-no. ABR-95094, Ciba Crop Protection, Greensboro, NC, USA, Aug. 12, 1995 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA329351/0331 (VV-372632)	N	N	Expired on 10/1/2012	SYN	-
IIA 7.1.1.2.1 CA 7.1.1.2.1	Buerge et al.	2003	Enantioselective Degradation of Metalaxyl in Soils: Chiral Preference Changes with Soil pH Not reported GLP Published	N/A	N/A	-	SYN	-
IIA 7.1.1.2.1 CA 7.1.1.2.1	Buser et al.	2002	Environmental behavior of the chiral acetamide pesticide metalaxyl: enantioselective degradation and chiral stability in soil. Not reported GLP Published	N/A	N/A	-	SYN	-
IIA 7.1.1.2.1 CA 7.1.1.2.1	Ellgehausen, H.	1994	Comparison of rate of degradation of [U-14C]-phenyl CGA 48988 with CGA 329351 in soil under laboratory conditions, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. PR 35/94, 19. Dec. 1994 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA48988/3745 (VV-375444)	N	N	Expired on 10/1/2012	SYN	-
IIA 7.1.1.2.1 CA 7.1.1.2.1	Ellgehausen, H.	1995a	Comparison of rate of degradation of [U-14C]-phenyl CGA 48988 with CGA 329351 in sandy soil Collombey under laboratory conditions, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. Proj.no. 95EH03, 12. July 1995 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA48988/3827 (VV-375509)	N	Y	New study never submitted before to this country	SYN	-

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IIA 7.1.1.2.1 CA 7.1.1.2.1	Jones, N.	2012	Metalaxyl-M - Calculation of Kinetic Endpoints from Laboratory Study Data for Metalaxyl-M and its Metabolites NOA409045 and CGA67868 Following FOCUS Kinetics Guidance Syngenta Syngenta - Jealott's Hill, Bracknell, United Kingdom, RAJ0930B Not GLP, not published Syngenta File No CGA329351_11481 (VV-627100)	N	N	N/A	SYN	-
IIA 7.1.1.2.1 CA 7.1.1.2.1	Kühne, R.	2007a	Metalaxyl-M - Re-evaluation of the kinetics of aerobic soil degradation studies under laboratory conditions following the guidance of the FOCUS Work Group on Degradation Kinetics Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, Ass07ROK01 Not GLP, not published Syngenta File No CGA329351/2372 (VV-25213)	N	N	N/A	SYN	-
IIA 7.1.1.2.1 CA 7.1.1.2.1	Marucchini et al.	2002	Stereoselective degradation of metalaxyl and metalaxyl-M in soil and sunflower plants Not GLP reported Published	N/A	N/A	-	SYN	-
IIA 7.1.1.2.1 CA 7.1.1.2.1	Monkiedje et al.	2005	Degradation of metalaxyl and mefenoxam and effects on the microbiological properties of tropical and temperate soils Not GLP reported Published	N/A	N/A	-	SYN	-
IIA 7.1.1.2.1 CA 7.1.1.2.1	Müller, M.D. and Buser, H.R.	1995	Environmental Behaviour of Acetamide Pesticide Stereoisomers. 2. Stereo- and Enantioselective Degradation in Sewage Sludge and Soil, Environ. Sci & Technol. 29, 2031-2037, 1995 Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Published	N/A	N/A	-	SYN	-
IIA 7.1.1.2.1 CA 7.1.1.2.1	Spiteller et al.	2003	Enantioselective degradation of pesticides in soil Not GLP reported Published	N/A	N/A	-	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.1.2.2 CA 7.1.1.2.2	Braxton, S.M. and Bird, R.McK.	1991	CGA 48988, Ridomil 2E, field dissipation, tobacco and bare soil, North Carolina, Ciba-Geigy Corp., Greensboro NC, USA, Rep.Nr. 23TBBS, 23.01.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished Syngenta File No CGA48988/2916 (VV-378382)	N	N	Expired on 10/1/2012	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Gizler A, Lakaschus S	2008	Metalaxyl-M-Soil dissipation study with A13947A, 480 SL, in or on soil in France 2007-2008 Syngenta - Jealott's Hill, Bracknell, United Kingdom Eurofins - Dr Specht & Partner, Hamburg, Germany, SYN-0734, T000727-07 GLP, not published Syngenta File No A13947A_11109 (VV-382490)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Guy, S.O.	1988a	Field dissipation study on Ridomil 5G for terrestrial uses on bareground in Hollandale, (296 pages), Ciba-Geigy Corp., USA, Rep.Nr. 1641-87-71-07-15B-01, 15.07.1988 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished Syngenta File No CGA48988/0288 (VV-377983)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Hardy I., Patel M.	2013	Metalaxyl-M - Kinetic Modelling Evaluation of Data from Field Soil Residue Studies Syngenta - Jealott's Hill, Bracknell, United Kingdom Battelle UK Ltd., Ongar, United Kingdom, NC/08/001E Not GLP, not published Syngenta File No CGA329351_11395 (VV-619039)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.1.2.2 CA 7.1.1.2.2	Jones, P.A.	1988	Field dissipation study on Ridomil 5G on bare ground, Ciba-Geigy Corp., USA, Rep.Nr. 87031, 19.12.1988 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished Syngenta File No CGA48988/0290 (VV-377992)	N	N	Expired on 10/1/2012	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Jones, P.A.	1989	Field dissipation study on Ridomil 5G on tomatoes, Ciba-Geigy Corp., USA, Rep.Nr. 87031, 10.01.1989 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished Syngenta File No CGA48988/0291 (VV-378288)	N	N	Expired on 10/1/2012	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Kühne R.O.	1998	Study on fate and behaviour of Metalaxyl-M (CGA 329351) in or on soil in Italy Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2383/97 GLP, not published Syngenta File No CGA329351/1028 (VV-312119)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Kühne R.	2000	Study on fate and behaviour of Metalaxyl-M (CGA 329351) in or on soil in France (South) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2036/98 GLP, not published Syngenta File No CGA329351/1210 (VV-312788)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.1.2.2 CA 7.1.1.2.2	Kühne R.	2003a	Study on Fate and Behaviour of Metalaxyl-M (CGA329351) in or on Soil in Italy Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 2027/99 GLP, not published Syngenta File No CGA329351/1729 (VV-378615)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Kühne R.	2003b	Study on Fate and Behaviour of Metalaxyl-M (CGA329351) in or on Soil in Switzerland Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 2028/99 GLP, not published Syngenta File No CGA329351/1731 (VV-378536)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Kühne R.	2003c	Study on Fate and Behaviour of Metalaxyl-M (CGA329351) in or on Soil in Switzerland Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 2029/99 GLP, not published Syngenta File No CGA329351/1732 (VV-378532)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Kühne R.	2003d	Study on Fate and Behaviour of Metalaxyl-M (CGA329351) in or on Soil in Spain Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 2057/99 GLP, not published Syngenta File No CGA329351/1733 (VV-378620)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.1.2.2 CA 7.1.1.2.2	Kühne R.	2003e	Study on Fate and Behaviour of Metalaxyl-M (CGA329351) in or on Soil in France (South) Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 2030/99 GLP, not published Syngenta File No CGA329351/1740 (VV-378577)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Kühne R.	2007b	Metalaxyl-M - Re-evaluation of the kinetics of field soil dissipation studies conducted in Europe following the guidance of the FOCUS Work Group on Degradation Kinetics Not Known Syngenta Crop Protection AG, Basel, Switzerland, Ass07ROK03 Not GLP, not published Syngenta File No CGA329351/2373 (VV-416455)	N	N	N/A	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Offizorz, P. and Ressler, H.	1991a	Field soil dissipation rate determination of metalaxyl, RCC GmbH, Rossdorf, Germany, Rep. Nr. 171314, dated 13.02.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland Not GLP Unpublished Syngenta File No CGA48988/3345 (VV-378384)	N	N	N/A	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Offizorz, P. and Ressler, H.	1991b	Field soil dissipation rate determination of metalaxyl, RCC GmbH, Rossdorf, Germany, Rep. Nr. 171325, 13.02.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland Not GLP Unpublished Syngenta File No CGA48988/3346 (VV-378385)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.1.2.2 CA 7.1.1.2.2	Offizorz, P. and Ressler, H.	1991c	Field soil dissipation rate determination of metalaxyl, RCC GmbH, Rossdorf, Germany, Rep. Nr. 171336, 13.02.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland Not GLP Unpublished Syngenta File No CGA48988/3347 (VV-378387)	N	N	N/A	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Offizorz, P. and Ressler, H.	1991d	Field soil dissipation rate determination of metalaxyl, RCC GmbH, Rossdorf, Germany, Rep. Nr. 223209, 21.03.1991 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland Not GLP Unpublished Syngenta File No CGA48988/3339 (VV-378062)	N	N	N/A	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Simon P.	2008	Metalaxyl-M - Soil Dissipation Study with A13947A, 480 SL, in or on Soil in Northern Germany in 2007-2008 Syngenta - Jealott's Hill, Bracknell, United Kingdom Syngenta Agro GmbH, Maintal, Germany, T012218-05 GLP, not published Syngenta File No A13947A_11110 (VV-382521)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.1.2.2 CA 7.1.1.2.2	Stolze K.	2003	Determination of Residues of CGA329351 in Bare Ground Soil after Application of NAD 21030 F on Bare Ground in Denmark 1999. Test product: NAD 21030 F - A 9408 B, EC480. (Denmark 1999) Syngenta Agro GmbH, Maintal, Germany Syngenta Agro GmbH, Maintal, Germany, gb31099 2123/99 GLP, not published Syngenta File No CGA329351/1730 (VV-328615)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.1.2.2 CA 7.1.1.2.2	Wiesner F., Breyer N.	2012	Metalaxyl-M - Storage Stability Study of Residues of Metalaxyl-M and its Metabolite NOA409045 in Two Different Soil Types Syngenta Eurofins Agrosience Services Chem GmbH, Hamburg, Germany, S10-03665_INT_1 GLP, not published Syngenta File No CGA329351_11491 (VV-117127)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.2.1 CA 7.1.2.1	Dorn R.	2001b	Adsorption/Desorption of CGA 48988 in Soil “Birkenheide” Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, NOV05 GLP, not published Syngenta File No CGA48988/5020 (VV-312747)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.2.1 CA 7.1.2.1	Dorn R., Hein W.	2002	Adsorption/Desorption of CGA329351 in Four Soils Syngenta Crop Protection AG, Basel, Switzerland SLFA - Neustadt, Neustadt, Germany, NOV08 GLP, not published Syngenta File No CGA329351/1552 (VV-326551)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.2.1 CA 7.1.2.1	Gardner D S; Branham B E	2001	Effect of turfgrass cover and irrigation on soil mobility and dissipation of mefenoxam and propiconazole. Not GLP reported Published	N/A	N/A	-	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.2.1 CA 7.1.2.1	Guth, J.A.	1978a	Adsorption and desorption of CGA 48988 (Ridomil) in various soil types, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 35/78, 15.06.1978 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA48988/0180 (VV-347070)	N	N	N/A	SYN	-
IIA 7.1.2.1 CA 7.1.2.1	Miner P.	2012a	[14C] - Metalaxyl-M - Adsorption and Desorption Properties in Multiple Soils Syngenta Ricerca Biosciences, LLC, Concord, OH, USA, 026137-1 GLP, not published Syngenta File No CGA329351_50818 (VV-401772)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.2.1 CA 7.1.2.1	Phaff R.	1999	Adsorption/desorption of CGA 329351 in various soils Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 98RP05 GLP, not published Syngenta File No CGA329351/1170 (VV-309567)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.2.1 CA 7.1.2.1	Spare, W.C.	1987	Adsorption/desorption of 14C-metalaxyl, Agrisearch Inc., Frederick MD, Rep.Nr. 1288, 23.09.1987 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA48988/0181 (VV-346879)	N	N	Expired on 10/1/2012	SYN	-

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IIA 7.1.2.1 CA 7.1.2.1	Spare, W.C.	1995	Adsorption/desorption of 14C-CGA 329351 by the batch equilibrium method on representative agricultural soils, Agriseach Inc., Frederick MD, Project.Nr. 12220, December 5, 1995, Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA329351/0332 (VV-375525)	N	N	Expired on 10/1/2012	SYN	-
IIA 7.1.2.2 CA 7.1.2.2	Dorn R.	2001c	Adsorption / Desorption of NOA 409045 in four Soils (metabolite to CGA 329351) Syngenta Crop Protection AG, Basel, Switzerland SLFA, Staat. Lehr-u.Forschungsanst.für Landwirtschaft, Neustadt, Germany, NOV13 GLP, not published Syngenta File No NOA409045/0012 (VV-333340)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.2.2 CA 7.1.2.2	Dorn R.	2001d	Adsorption/Desorption of CGA 62826 in Soil “Birkenheide” Syngenta Crop Protection AG, Basel, Switzerland SLFA - Neustadt, Neustadt, Germany, NOV12 GLP, not published Syngenta File No CGA62826/0022 (VV-313246)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.2.2 CA 7.1.2.2	Heinis, T.	1994a	Soil adsorption of CGA 62826, Ciba-Geigy Ltd., Basel, Switzerland, Rep. Nr. 94 HT 04, 10.11.1994 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA62826/0004 (VV-375522)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.2.2 CA 7.1.2.2	Miner P.	2012b	SYN546520 - Adsorption and Desorption of [14C]-SYN546520 in Four Soils Syngenta Ricerca Biosciences, LLC, Concord, OH, USA, 027992-1 GLP, not published Syngenta File No SYN546520_50002 (VV-401773)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.2.2 CA 7.1.2.2	Miner P.	2012c	CGA067868 - Adsorption and Desorption of [14C]-CGA067868 in Five Soils Syngenta Ricerca Biosciences, LLC, Concord, OH, USA, 028657-1 GLP, not published Syngenta File No CGA092370_50000 (VV-402377)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.2.2 CA 7.1.2.2	Reischmann F.J.	1998	Adsorption / Desorption of 14C-NOA 409045 in various soils Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 98RF01 GLP, not published Syngenta File No NOA409045/0010 (VV-310920)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.2.1 CA 7.1.2.2	Spare, W.C.	1996	Adsorption/desorption of 14C-CGA 62826 by the batch equilibrium method on representative agricultural soils, Agrisearch Inc., Frederick MD, Project. Nr. 12225, August 19, 1996 Owned by Novartis Crop Protection AG, Basel, Switzerland Submitted by Novartis Crop Protection AG, Basel, Switzerland GLP Unpublished Syngenta File No CGA62826/0009 (VV-378114)	N	N	Expired on 10/1/2012	SYN	-

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IIA 7.1.3.1 CA 7.1.3.1	Guth, J.A.	1976a	Leaching model study with the fungicide CGA 48988 in four standard soils, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 30/76, 27.09.1976 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA48988/0182 (VV-377986)	N	N	N/A	SYN	-
IIA 7.1.3.2 CA 7.1.3.2	Fathulla,	1996b	Column leaching characteristics of aged 14C-CGA 329351 in four soil types Project CHW 6117-284, Corning Hazleton Inc. Madison, WI, USA, Preliminary data Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland GLP Unpublished Syngenta File No CGA329351/0328 (VV-372638)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.3.2 CA 7.1.3.2	Guth, J.A.	1978b	Leaching characteristics of aged 14C-CGA 48988 (Ridomil ®) residues in two standard soils, Ciba-Geigy Ltd., Basle, Switzerland, Rep. Nr. 33/78, 10.06.1978 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA48988/0184 (VV-377988)	N	N	N/A	SYN	-
IIA 7.1.3.2 CA 7.1.3.2	Suter, P.	1985	Leaching characteristics of aged residues of 14C-metalaxyl (RIDOMIL) in Speyer soil, Ciba-Geigy Ltd., Basle, Switzerland, Rep.Nr. 33/85, 15.10.1985 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA48988/0185 (VV-346598)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.1.3.3 CA 7.1.3.3	Ford, S.	2013	Metalaxyl-M : Inverse modeling of outdoor lysimeters to derive a formation fraction for the soil metabolite CGA108906. JSC International Limited, UK. Rep. Nr SYN/41/01-01 Not GLP Unpublished Syngenta File No CGA108906_10001 (VV-627421)	N	N	N/A	SYN	-
IIA 7.1.3.3 CA 7.1.3.3	Kubiak, R.	1995a	Degradation and leaching of 14C-metalaxyl in two sand lysimeters under outdoor conditions after application to potatoes, SLFA FB Phytomedizin, Neustadt/Weinstrasse, Study No. CIBO2, 2.1995 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA48988/3732 (VV-372496)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.1.3.3 CA 7.1.3.3	Kubiak, R.	1995b	Degradation and leaching of 14C-metalaxyl in two sand lysimeters under outdoor conditions after application to vine - 2nd Interim Report, SLFA FB Phytomedizin, Neustadt/Weinstrasse, Study No. CIBO3, April 13, 1995 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA48988/3489 (VV-372629)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.2.1.1 CA 7.2.1.1	Ellgehausen, H.	1996b	Hydrolysis of 14C.labelled CGA 329351 under laboratory conditions, Ciba-Geigy Ltd., Basle, Project No 95EH05 Owned by Ciba-Geigy Ltd., Basle, Switzerland, 3. January 1996 Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA329351/0330 (VV-372644)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.2.1.2 CA 7.2.1.2	Ellgehausen, H.	1995c	Aqueous photolysis of 14C.labelled CGA 329351 at pH 7 under artificial sunlight conditions, Ciba-Geigy Ltd., Basle, Project No 95EH04, 20. December 1995 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA329351/0329 (VV-377898)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.2.1.2 CA 7.2.1.2	Phaff, R.	1995	Rate and quantum yield of the direct phototransformation of CGA 329351 under laboratory conditions in water, Project 95RP02, Oct. 26, 1995, Ciba-Geigy Ltd., Basle 24.01.1995. Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland. GLP Unpublished Syngenta File No CGA329351/0297 (VV-377631)	N	N	Expired on 10/1/2012	SYN	-
IIA 7.2.1.3.1 CA 7.2.1.3.1	Grade, R.	1995	Report on the test for ready biodegradability of CGA 329351 (enantiomer of CGA 489888) in the carbondioxide evolution test, Project No.: 953607, Ecotoxicology, Product Safety, Ciba-Geigy Ltd., Basle Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA329351/0323 (VV-377623)	N	N	Expired on 10/1/2012	SYN	-
IIA 7.2.1.3.2 CA 7.2.1.3.2	Morgenroth, U.	1994	14C-CGA 48988 (Metalaxyl). Degradation and metabolism in aquatic systems, RCC AG, Itingen, Switzerland, Rep. Nr. 341076, 03.03.1994, include. amendment of August 23, 1994 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA48988/3521 (VV-375216)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.2.1.3.2 CA 7.2.1.3.2	Vithala, R.	1992	Anaerobic Aquatic Metabolism of 14C-Metalaxyl, Ciba-Geigy Corp., Greensboro NC, USA, Rep.Nr. 005-001-007-89, 13.01.1992 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA48988/3131 (VV-349943)	N	N	Expired on 10/1/2012	SYN	-
IIA 7.2.1 CA 7.2.1	Hardy, I	2014	Metalaxyl – Kinetic Modelling Analysis of Data from a Water Sediment Study to Derive Modelling and Persistence Endpoint DT50 Values, Report Number NC/14/028A, Battelle UK Ltd., Chelmsford, Essex, CM2 5LB, UK.Syngenta File No. CGA048988_11217 Not GLP Unpublished Syngenta File No CGA048988_11217 (VV-628482)	N	N	N/A	SYN	-
IIA 7.2.2 CA 7.2.2	Burkhard, N.	1977	Volatilization of CGA 48988 from soil under laboratory conditions, Ciba-Geigy Ltd., Basle, Rep.Nr. 29/77, 27.05.1977 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA48988/0186 (VV-346603)	N	N	N/A	SYN	-
IIA 7.2.2.2 CA 7.2.2	Krauss, J.	1992	Volatilization of CGA 48988 from bean leaves under indoor conditions after spray application of [14C-phenyl] labelled material, Ciba-Geigy Ltd., Basle, Rep.Nr. 12-92, 22.05.1992 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland GLP Unpublished Syngenta File No CGA48988/3203 (VV-378066)	N	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.2.2 CA 7.2.2	Stamm, E.	1995	Atmospheric oxidation of CGA 329351 by hydroxyl radicals; rate estimation, Ciba Crop Protection Basel, Report 95A95039SM, May 9, 1995 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basle, Switzerland Not GLP Unpublished Syngenta File No CGA329351/0072 (VV-372646)	N	N	N/A	SYN	-
IIA 7.2.2 CA 7.2.2	Hayes, S E	2014	Metalaxyl – Calculation of half-life by reaction with atmospheric hydroxyl radicals. Report Number RAJ1052B, Syngenta Ltd., Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY, UK. Not GLP Unpublished Syngenta File No CGA329351_11644 (VV-407120)	N	N	N/A	SYN	-
IIA 7.3.1 CA 7.3.1	De Schampheleire et al.	2008	Evaporation drift of pesticides active ingredients. Not GLP reported Published	N/A	N/A	-	SYN	-
IIA 7.4 CA 7.4	Amic S.	2011	Metalaxyl-M, NOA409045 and CGA108906 - Residue storage stability study in surface water and ground water under freezer and refrigeration storage conditions Syngenta Eurofins - ADME Bioanalyses, Vergeze, France, T000258-08-REG GLP, not published Syngenta File No CGA329351_11469 (VV-397972)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.4 CA 7.4	Balu, K.	1985b	Ridomil groundwater monitoring study results during 1983 - 1984, Ciba-Geigy Corp., USA, Rep.Nr. EIR-85023, 09.12.1985 Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA48988/0293 (VV-341490)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.4 CA 7.4	Behl, E.,US EPA.	1995	Risk assessment example for Schmallenberg conference : Metalaxyl Not GLP Published	N/A	N/A	-	SYN	-
IIA 7.4 CA 7.4	Edwards P., Saludas J.	2012	Metalaxyl-M - Retrospective Groundwater Monitoring for Metalaxyl-M (CGA329351) and its Metabolites NOA409045 and CGA108906 in France 2007 to 2011 Syngenta Eurofins - ADME Bioanalyses, Vergeze, France, SCE Toulouse, Ramonville, Saint Agne, Toulouse, France, T002243-06-INT/1 GLP, not published Syngenta File No CGA329351_11483 (VV-401614)	N	Y	New study never submitted before to this country	SYN	-
IIA 7.4 CA 7.4	Egli, H.	1998a	Metalaxyl in Monitoring Studies Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No CGA48988/5083 (VV-25203)	N	N	N/A	SYN	-
IIA 7.4 CA 7.4	Egli, H., Plücken U., Watson G.	1998b	Comments on Canadian metalaxyl water monitoring report Owned by Ciba-Geigy Ltd., Basle, Switzerland Submitted by Ciba-Geigy Ltd., Basel, Switzerland Not GLP Unpublished Syngenta File No	N	N	N/A	SYN	-
IIA 7.4 CA 7.4	Léger, D., Ernst, B., Julien, G., Boldon, M., Mutch, J., Kinnie, B., Milburn, P., Stypa, M., Purdy, J., and Fairbairn D.,	1994-95	Metalaxyl Ground Water Study - 1994-95 Environment Canada Atlantic Region Not GLP Unpublished Syngenta File No	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 7.4 CA 7.4	Robinson N.	2007	Water Monitoring Study in the Ribatejo, Beira Litoral, Oeste and Douro Regions of Portugal, 1999-2007 Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, TMJ5071B Not GLP, not published Syngenta File No CGA329351/2562 (VV-380693)	N	N	N/A	SYN	-
IIA 7.4 CA 7.4	Liss D., Naeb O.	2014	Metalaxyl-M – Elucidation of Residue Findings in Groundwater at Jynde vad Test Site, Denmark – Final report. SGS Institut Fresenius GmbH, Taunusstein, Germany. Report Nr IF-13/02826320 Not GLP, not published Syngenta File No CGA329351_11641 (VV-406206)	N	N	N/A	SYN	-
IIA 7.4 CA 7.4	Jones N., Seville T.	2014	Statement to RMS Belgium regarding Metalaxyl-M findings in DK groundwater Syngenta Not GLP, not published Syngenta File No CGA329351_11655 (VV-117984)	N	N	N/A	SYN	-
IIA 8.1.1 [Previously evaluated in DAR July 1999]	Johnson, A.	1995	CGA 329351, Acute oral toxicity to bobwhite quail, Report N° CBG 749, Huntingdon Research Centre, UK, 21.12.1995 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 329351/310 Syngenta File No CGA329351/0310 (VV-372649)	Y	N	Expired on 10/1/2012	SYN	-
IIA 8.1.1 [Previously evaluated in DAR July 1999]	Palmer S.J., Campbell S.M., Beavers J.B.	1995a	An acute oral toxicity test with the northern bobwhite, Report N° 108-375, Wildlife International Ltd., USA, August 21, 1995 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 329351/301 Syngenta File No CGA329351/0301 (VV-372651)	Y	N	Expired on 10/1/2012	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIA 8.1.3 [Previously evaluated in DAR July 1999]	Beavers, J.B.	1980a	One-generation reproduction study - bobwhite quail, CGA 48988 technical, Wildlife International Ltd., USA, Rep.Nr. 108-175, 27.10.1980 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle Not GLP, unpublished Ciba file N° 48988/151 Syngenta File No CGA48988/0151 (VV-378272)	Y	N	N/A	SYN	-
IIA 8.1.3 [Previously evaluated in DAR July 1999]	Beavers, J.B.	1980b	One-generation reproduction study - Mallard duck, CGA 48988 technical, Wildlife International Ltd., USA, Rep.Nr. 108-176, 27.10.1980 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle Not GLP, unpublished Ciba file N° 48988/152 Syngenta File No CGA48988/0152 (VV-341718)	Y	N	N/A	SYN	-
IIA 8.1.3 [Previously evaluated in DAR addendum May 2000]	Taliaferro M.C., Miller V. C.	1998a	The Reproductive Toxicity Test of CGA-329351 Technical with the Northern Bobwhite (Colinus virginianus). Novartis Crop Protection, Inc. GLP, not published Novartis File No 573-97 Syngenta File No CGA329351/1071 (VV-312458)	Y	N	Expired on 10/1/2012	SYN	-
IIA 8.1.3 [Previously evaluated in DAR addendum May 2000]	Taliaferro M.C., Miller V. C.	1998b	The Reproductive Toxicity Test of CGA-329351 with the Mallard Duck (Anas platyrhynchos). Novartis Crop Protection, Inc. GLP, not published Novartis File No 627-97 Syngenta File No CGA329351/1072 (VV-312459)	Y	N	Expired on 10/1/2012	SYN	-

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IIA 8.2.1 [Previously evaluated in DAR July 1999]	Rufli, H.	1994b	Report on the acute toxicity test of CGA 329351 techn. (Enantiomer of CGA 48988) to Rainbow Trout, Project Report 933718, Ecotoxicology, Ciba-Geigy, Basle, 1.12.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 329351/25 Syngenta File No CGA329351/0025 (VV-372551)	Y	N	Expired on 10/1/2012	SYN	-
IIA 8.2.1 [Previously evaluated in DAR July 1999]	Drott K.R., Swigert J.P.	1995a	CGA 329351, A 96-hour static acute toxicity test with the rainbow trout, Oncorhynchus mykiss, Report N° 108A-164, Wildlife International Ltd., USA, September 15, 1995 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 329351/299 Syngenta File No CGA329351/0299 (VV-372553)	Y	N	Expired on 10/1/2012	SYN	-
IIA 8.2.1 [Previously evaluated in DAR July 1999]	Memmert, U., Knoch, E.	1991a	Acute toxicity of CGA 62826 to Rainbow trout in a semi-static test (96h), Project Report 251054, RCC GmbH, Rossdorf, Germany, 18.12. 1991 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 62826/3 Syngenta File No CGA62826/0003 (VV-373671)	Y	N	Expired on 10/1/2012	SYN	-
IIA 8.2.1 [Previously evaluated in DAR July 1999]	Memmert, U., Knoch, E.	1992a	Acute toxicity of CGA 67868 to Rainbow trout in a semi-static test (96h), Project Report 257051, RCC GmbH, Rossdorf, Germany, 13.01. 1992 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 67868/2 Syngenta File No CGA67868/0002 (VV-375983)	Y	N	Expired on 10/1/2012	SYN	-

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IIA 8.2.1 [Previously evaluated in DAR July 1999]	Rufli, H.	1994a	Report on the acute toxicity test of CGA 108906 techn. (Metabolite of CGA 48988) to Rainbow Trout, Project Report 943542, Ecotoxicology, Ciba-Geigy, Basel, 11.07.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 108906/3 Syngenta File No CGA108906/0003 (VV-372556)	Y	N	Expired on 10/1/2012	SYN	-
IIA 8.2.2.1 [Evaluated in RAR November 2013]	Rufli H.	2000	Prolonged toxicity test of CGA 329351 to Rainbow trout (Oncorhynchus mykiss) under flow-through conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2003535 GLP, not published Syngenta File No CGA329351/1305 (VV-312121)	Y	Y	New study never submitted before to this country	SYN	-
IIA 8.2.2.1 [Evaluated in RAR November 2013]	Rufli H.	2000a	Prolonged toxicity test of CGA 62826 to Rainbow trout (Oncorhynchus mykiss) under flow-through conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2003533 GLP, not published Syngenta File No CGA62826/0020 (VV-312122)	Y	Y	New study never submitted before to this country	SYN	-
IIA 8.2.2.2 [Previously evaluated in DAR July 1999]	LeBlanc, G.A.	1980a	The toxicity of CGA 48988 to fathead minnow (Pimephales promelas) eggs and fry, Bionomics Aquatic Tox. Lab., Mass., USA, Rep.Nr. BW-80-4-642, 01.04.1980 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 48988/157 Syngenta File No CGA48988/0157 (VV-378274)	Y	Y	New study never submitted before to this country	SYN	-

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IIA 8.2.3 [Previously evaluated in DAR July 1999]	Ladd, S.A., Wilson, W.G.	1979a	Accumulation and Elimination of 14C-Residues by Bluegill sunfish (Lepomis macrochirus) exposed to phenyl labelled-14C-CGA-48988, BW-78-10328, EG&G, Bionomics, Wareham, Mass., USA, 01.04.1979 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle Not GLP, unpublished Ciba file N° 48988/202 Syngenta File No CGA48988/0202 (VV-346599)	Y	N	N/A	SYN	-
IIA 8.2.3 [Previously evaluated in DAR July 1999]	Ladd, S.A., Enos, J.	1979b	Kinetics of phenyl labelled 14C-CGA-48988 in a model aquatic ecosystem, BW-79-2-401, EG&G, Bionomics, Wareham, Mass., USA, 01.02.1979 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle Not GLP, unpublished Ciba file N° 48988/203 Syngenta File No CGA48988/0203 (VV-346600)	Y	N	N/A	SYN	-
IIA 8.2.4 [Previously evaluated in DAR July 1999]	Grade, R.	1994b	Report on the acute toxicity test of CGA 329351 tech. (Enantiomer of CGA 48988) on Daphnia (Daphnia magna Strauss), Project Report 933719, Ecotoxicology, Ciba-Geigy, Basel, 1.12.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 329351/26 Syngenta File No CGA329351/0026 (VV-372558)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.2.4 [Previously evaluated in DAR July 1999]	Drottar, K.R., Swigert J.P.	1995b	A 48-hour static acute toxicity test with the cladoceran, Daphnia magna, Report N° 108A-166, Wildlife International Ltd., USA, August 21, 1995 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 329351/298 Syngenta File No CGA329351/0298 (VV-372560)	N	N	Expired on 10/1/2012	SYN	-

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IIA 8.2.4 [Previously evaluated in DAR July 1999]	Drott K.R., Swigert J.P.	1995c	A 96-hour shell deposition test with the eastern oyster, <i>Crassostrea virginica</i> , Report N° 108A-165, Wildlife International Ltd., USA, September 15, 1995 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 329351/300 Syngenta File No CGA329351/0300 (VV-375513)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.2.4 [Previously evaluated in DAR July 1999]	Hoberg, J.R.	1989	Acute toxicity to Mysid shrimp under flow-through conditions, Springborn, Wareham, Mass., Rep.Nr. 89-10-3125, 26.10.1989 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 48988/162 Syngenta File No CGA48988/0162 (VV-341715)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.2.4 [Previously evaluated in DAR July 1999]	Dionne, E.Y.	1989	Acute toxicity to Eastern oysters under flow-through conditions, Springborn, Wareham, Mass., Rep.Nr. 89-9-3093, 26.10.1989 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 48988/163 Syngenta File No CGA48988/0163 (VV-341716)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.2.4 [Previously evaluated in DAR July 1999]	Memmert, U., Knoch, E.	1991b	48-hour toxicity of CGA 62826 to <i>Daphnia magna</i> (OECD-Immobilization -Test), Project Report 251032, RCC GmbH, Rossdorf, Germany, 18.12.1991 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 62826/1 Syngenta File No CGA62826/0001 (VV-373676)	N	N	Expired on 10/1/2012	SYN	-

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IIA 8.2.4 [Previously evaluated in DAR July 1999]	Memmert U., Knoch, E.	1991c	48-hour toxicity of CGA 67868 to Daphnia magna (OECD-Immobilization -Test), Project Report 257038, RCC GmbH, Rossdorf, Germany, 11.12.1991 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 67868/1 Syngenta File No CGA67868/0001 (VV-375985)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.2.4 [Previously evaluated in DAR July 1999]	Grade, R.	1994a	Report on the acute toxicity test of CGA 108906 tech. (Metabolite of CGA 48988) on Daphnia, Project Report 943524, Ecotoxicology, Ciba-Geigy, Basel, 24.06.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 108906/2 Syngenta File No CGA108906/0002 (VV-372562)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.2.5 [Evaluated in RAR November 2013]	Pfeifle V.	2000	Effects of CGA 329351 tech. on the reproduction of Daphnia magna Straus in a semi-static test Novartis Crop Protection AG, Basel, Switzerland Solvias AG, Basel, Switzerland, G 597 22 GLP, not published Syngenta File No CGA329351/1308 (VV-312123)	N	Y	New study never submitted before to this country	SYN	-
IIA 8.2.5 [Evaluated in RAR November 2013]	Pfeifle V.	2000a	Effect of CGA 62826 on the reproduction of Daphnia magna Strauss in a semistatic test Novartis Crop Protection AG, Basel, Switzerland Solvias AG, Basel, Switzerland, G 598 22 GLP, not published Syngenta File No CGA62826/0021 (VV-312124)	N	Y	New study never submitted before to this country	SYN	-

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IIA 8.2.6 [Previously evaluated in DAR July 1999]	Grade, R.	1994d	Report on the growth inhibition test of CGA 329351 tech. (Enantiomer of CGA 48988) to green alga (Scenedesmus subspicatus), Project Report 933720, Ecotoxicology, Ciba-Geigy, Basel, 1.12.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 329351/27 Syngenta File no CGA329351/0027 (VV-372565)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.2.6 [Previously evaluated in DAR July 1999]	Grade, R.	1995	Report on the growth inhibition test of CGA 48988 tech. to Green Algae (Scenedesmus subspicatus), Project Report 943628, Ecotoxicology, Ciba-Geigy, Basel, 24.03.1995 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 48988/3737 Syngenta File No CGA48988/3737 (VV-377612)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.2.6 [Previously evaluated in DAR July 1999]	Memmert, U., Knoch, E.	1991d	Toxicity of CGA 62826 to Scenedesmus subspicatus (Algae Growth Inhibition Test), Project Report 251010, RCC GmbH, Rossdorf, Germany, 18.12.1991 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 62826/2 Syngenta File No CGA62826/0002 (VV-373680)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.2.6 [Previously evaluated in DAR July 1999]	Memmert, U., Knoch, E.	1992b	Toxicity of CGA 67868 to Scenedesmus subspicatus (Algae Growth Inhibition Test), Project Report 257016, RCC GmbH, Rossdorf, Germany, 13.01.1992 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 67868/3 Syngenta File No CGA67868/0003 (VV-375987)	N	N	Expired on 10/1/2012	SYN	-

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IIA 8.2.6 [Previously evaluated in DAR July 1999]	Grade, R.	1994c	Report on the growth inhibition test of CGA 108906 tech. (Metabolite of CGA 48988) to Green Algae, Project Report 943525, Ecotoxicology, Ciba-Geigy, Basle, 24.06.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 108906/1 Syngenta File No CGA108906/0001 (VV-372567)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.2.6 [Evaluated in RAR November 2013]	Weber K.	2011	NOA409045 - Testing effects on the single cell green alga Pseudokirchneriella subcapitata Syngenta Eurofins - GAB, Niefern Öschelbronn, Germany, S10-03792 GLP, not published Syngenta File No NOA409045_10002 (VV-397490)	N	Y	New study never submitted before to this country	SYN	-
IIA 8.3.1.1 [Previously evaluated in DAR July 1999]	Palmer S.J., Beavers J.B.	1995c	An acute contact toxicity with the honey bee, Report N° 108-376, Wildlife International Ltd., USA, August 21, 1995 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 329351/303 Syngenta File No CGA329351/0303 (VV-372835)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.3.1.1 [Previously evaluated in DAR July 1999]	Kleiner, R.	1994	Testing to Honeybee-Apis mellifera L. (Laboratory) According to EPPO Guideline No. 170, Report No.:941048056, 05.12.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 48988/3642 Syngenta File No CGA48988/3642 (VV-355513)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.3.1.1 [Evaluated in RAR November 2013]	Kling A.	2011	Metalaxyl-M (CGA329351) - Acute Oral and Contact Toxicity to the Honeybee Apis mellifera L. in the Laboratory Syngenta Crop Protection AG, Basel, Switzerland Eurofins - GAB, Niefern Öschelbronn, Germany, S10-03785 GLP, not published Syngenta File No CGA329351_11459 (VV-397454)	N	Y	New study never submitted before to this country	SYN	-

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IIA 8.4.1 [Previously evaluated in DAR July 1999]	Rufli, H.	1997	Acute toxicity test of CGA 329351 (enantiomer of CGA 48988) to earthworm (Eisenia foetida). Report n° 973501, Novartis Crop Protection AG, Ecotoxicology Dept., Basel, Switzerland, July 28, 1997 Owned by Novartis Crop Protection AG Submitted by Novartis Crop Protection AG GLP, unpublished Ciba file N° 329351/689 Syngenta File No CGA329351/0689 (VV-548527)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.4.1 [Previously evaluated in DAR July 1999]	Vial, A.	1990	Acute toxicity test of CGA 48988 techn. to Earthworm (Eisenia foetida foetida), Ciba-Geigy Ltd., Basle, Rep.Nr. 901034, 27.04.1990 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 48988/168 Syngenta File No CGA48988/0168 (VV-378275)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.4.1 [Previously evaluated in DAR addendum May 2000]	Bätscher R.	1999a	Acute toxicity of NOA 409045 (Metabolite of CGA 329351) to earthworms (Eisenia foetida) in a 14-day static test. Novartis Crop Protection AG GLP, not published Novartis File No 983845 Syngenta File No NOA409045/0002 (VV-312125)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.4.1 [Previously evaluated in DAR addendum May 2000]	Bätscher R.	1999b	Acute toxicity of CGA 108906 (Metabolite of CGA 329351) to earthworms (Eisenia foetida) in a 14-day static test. Novartis Crop Protection AG GLP, not published Novartis File No 983847 Syngenta File No CGA108906/0010 (VV-312126)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.4.2 [Evaluated in RAR November 2013]	Friedrich S.	2011	Metalaxyl-M (CGA329351) - Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil Syngenta BioChem Agrar, Gerichshain, Germany, 11 10 48 027 S GLP, not published Syngenta File No CGA329351_11468 (VV-398183)	N	Y	New study never submitted before to this country	SYN	-

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IIA 8.4.2 [Evaluated in RAR November 2013]	Friedrich S.	2011a	NOA409045 - Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 11 10 48 026 S GLP, not published Syngenta File No NOA409045_10001 (VV-397525)	N	Y	New study never submitted before to this country	SYN	-
IIA 8.4.2 [Evaluated in RAR November 2013]	Friedrich S.	2011b	CGA108906 - Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 11 10 48 031 S GLP, not published Syngenta File No CGA108906_10000 (VV-397526)	N	Y	New study never submitted before to this country	SYN	-
IIA 8.4.2 [Evaluated in RAR November 2013]	Friedrich S.	2011c	Metalaxyl-M (CGA329351) - Effects on the reproduction of the Collembolans Folsomia candida Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 11 10 48 028 S GLP, not published Syngenta File No CGA329351_11456 (VV-397043)	N	Y	New study never submitted before to this country	SYN	-
IIA 8.5 [Previously evaluated in DAR July 1999]	Völkel, S.	1992	The effects of CGA 48988-Metalaxyl on soil respiration and nitrification, RCC AG, Itingen, Switzerland, Rep.Nr. 305785, 24.02.1992 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 48988/3122 Syngenta File No CGA48988/3122 (VV-378365)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.5 [Previously evaluated in DAR addendum May 2000]	Völkel W.	1999a	NOA 409045: The effects on soil respiration and nitrification. Novartis Crop Protection AG GLP, not published Novartis File No 983846 Syngenta File No NOA409045/0009 (VV-312456)	N	N	Expired on 10/1/2012	SYN	-

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IIA 8.5 [Previously evaluated in DAR addendum May 2000]	Völkel W.	1999b	CGA 108906: The effects on soil respiration and nitrification. Novartis Crop Protection AG GLP, not published Novartis File No 983848 Syngenta File No CGA108906/0011 (VV-312455)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.7 [Previously evaluated in DAR July 1999]	Grade, R.	1996	Report on the test for activated sludge respiration inhibition of CGA 329351 (enantiomer of CGA 48988), Project Report 953610, Ecotoxicology, Ciba-Geigy Basel, January 10, 1996 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 329351/324 Syngenta File No CGA329351/0324 (VV-377616)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.7 [Previously evaluated in DAR July 1999]	Weinstock, M.	1994	Report on the test for Activated Sludge Respiration Inhibition of CGA 48988 techn., Project Report 943512, Ecotoxicology, Ciba-Geigy Basel, 24.03.1994 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle GLP, unpublished Ciba file N° 48988/3528 Syngenta File No CGA48988/3528 (VV-377613)	N	N	Expired on 10/1/2012	SYN	-
IIA 8.7 [Previously evaluated in DAR July 1999]	Glisnki, D.J.	1979	Effects of CGA 48988 on the activated sludge process, Union carbide corporation Environmental services, Tarrytown, NY, USA, February 1979 Owned by Ciba-Geigy Ltd. Basle Switzerland Submitted by Ciba-Geigy Ltd. Basle Not GLP, unpublished Ciba file N° 48988/3492 Syngenta File No CGA48988/3492 (VV-377615)	N	N	N/A	SYN	-

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CP 1.4.1/ KIIIA1 2 / 01	Schneider B.	1996	Report on chemical composition Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, 46030 GLP, not published Syngenta File No CGA329351/0666 (VV-284459)	N	Y	New study never submitted before to this country	SYN	-
CP 1.4.1 CP 2.6/ KIIIA1 2 / 02 & KIIIA1 2.6.1 / 01	Das R.	2011	A9642C - Chemical characterization of batch POR1G31741 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 123586 GLP, not published Syngenta File No A9642C_10041 (VV-401051)	N	Y	New study never submitted before to this country	SYN	-
CP 2.1 CP 2.4 CP 2.5/ KIIIA1 2.1 / 01 & KIIIA1 2.4.1 / 01 & KIIIA1 2.4.2 / 01 & KIIIA1 2.5.2 / 01 & KIIIA1 2.5.3 / 01	Martin-Keusch C.	2011	A9642C - Physical properties of batch POR1G31741 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 123618 GLP, not published Syngenta File No A9642C_10042 (VV-401052)	N	Y	New study never submitted before to this country	SYN	-
CP 2.2/ KIIIA1 2.2.1 / 01	Schurch H.	1996	Report on explosive properties Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, PP-96/56C.EXP GLP, not published Syngenta File No CGA329351/0512 (VV-284162)	N	Y	New study never submitted before to this country	SYN	-

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CP 2.2/ KIIIA1 2.2.2 / 01	Jackson W.	2011	A9642C - Oxidising properties Syngenta Syngenta Technology & Projects, Huddersfield, United Kingdom, HT11/544 GLP, not published Syngenta File No A9642C_10036 (VV-397178)	N	Y	New study never submitted before to this country	SYN	-
CP 2.3/ KIIIA1 2.3.1 / 01	Schurch H.	1996a	Report on determination of flashpoint Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, PP-96/56C.FLP GLP, not published Syngenta File No CGA329351/0511 (VV-284160)	N	Y	New study never submitted before to this country	SYN	-
CP 2.3/ KIIIA1 2.3.3 / 01	Schurch H.	1996b	Report on auto-ignition temperature of liquids Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Basel, Switzerland, PP-96/56C.AFG GLP, not published Syngenta File No CGA329351/0513 (VV-284163)	N	Y	New study never submitted before to this country	SYN	-
CP 2.7 CP 4.4/ KIIIA1 2.7.1 / 01 KIIIA1 4.1.3 / 01	Kundel P.	2012	A9642C - Storage Stability and Shelf Life Statement (2 weeks 54°C) in packaging made of HDPE Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 10484719 Not GLP, not published Syngenta File No A9642C_10043 (VV-401053)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CP 2.7.3	Fumeaux J.	2014	Metalaxyl-M – A9642C - Storage Stability and Shelf Life Statement (2 Years 20 °C) in Packaging Made of HDPE Summary Report Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, Report No 300018496 Not GLP, not published Syngenta File No. A9642C_10293 (VV-407142)	N	N	N/A	SYN	-
CP 2.7 CP 2.8.2 CP 2.8.6/ KIIIA1 2.7.4 / 01 & KIIIA1 2.8.2 / 01 & KIIIA1 2.8.7.1 / 01	Martin-Keusch C.	2011a	A9642C - Technical properties of bath POR1G131741 Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 123630 Not GLP, not published Syngenta File No A9642C_10044 (VV-401054)	N	N	N/A	SYN	-
CP 2.10/ KIIIA1 2.10.1 / 01 & KIIIA1 2.10.2 / 01	Khot S.	2012	A9642C - Technical Properties of batch POR1G31741 on treated seed (Spinach) Syngenta Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMN10737 Not GLP, not published Syngenta File No A9642C_10045 (VV-401055)	N	N	N/A	SYN	-
CP 2.10/ KIIIA1 2.10.1 / 02 & KIIIA1 2.10.2 / 02	Khot S.	2012a	A9642C - Technical Properties of batch POR1G31741 on treated seed (Sunflower) Syngenta Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMN10738 Not GLP, not published Syngenta File No A9642C_10046 (VV-401056)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CP 5.1.1 CP 5.2/ KIIIA1 5.2.1 / 01	Schneider B.	1997	Analytical method CGA 329351 in formulation (ES 350) by gas chromatography Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland, AF-1235/2 Not GLP, not published Syngenta File No CGA329351/0685 (VV-123846)	N	N	N/A	SYN	-
CP 5.1.1 CP 5.2/ KIIIA1 5.2.1 / 02	Stampf P.	2002	Analytical method content of CGA 329351 and CGA 351920 in A-9642 C by chiral LC Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland, AFA-1235/2 Not GLP, not published Syngenta File No CGA329351/1666 (VV-123845)	N	N	N/A	SYN	-
CP 5.1.1 CP 5.2/ KIIIA1 5.2.1 / 03	Schneider B.	1997a	Report on validation of analytical method Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland, 52651 GLP, not published Syngenta File No CGA329351/0687 (VV-284530)	N	Y	New study never submitted before to this country	SYN	-
CP 5.1.1 CP 5.2/ KIIIA1 5.2.1 / 04	Stampf P.	2002a	Report on validation of analytical method - AFA-1235/2 Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Basel, Switzerland, 109643 GLP, not published Syngenta File No CGA329351/1659 (VV-377419)	N	Y	New study never submitted before to this country	SYN	-
CP 5.1.1 CP 5.2/ KIIIA1 5.2.4 / 01	Stampf P.	2001	Analytical Method - 2,6-dimethylaniline in formulation (CGA 72649) in formulation Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland, AG-1837/2 Not GLP, not published Syngenta File No CGA329351/1563 (VV-127870)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CP 5.1.1 CP 5.2/ KIIIA1 5.2.4 / 02	Stampf P.	2001a	Validation of the analytical method - AG-1837/2 to analyze 2,6-dimethyl aniline (CGA 72649) in formulations Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection Mönchwil AG, Mönchwil, Switzerland, 112806 GLP, not published Syngenta File No CGA329351/1757 (VV-297091)	N	Y	New study never submitted before to this country	SYN	-
KIIIA1 7.1.1	Winkler G	1997	CGA 329351 350 ES (A-9642 C) -Acute oral toxicity in the rat. Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Stein, Switzerland, 963150 GLP Syngenta File No CGA329351/0531 (VV-353877)	Y	Y	New study never submitted before to this country	SYN	-
KIIIA1 7.1.2	Winkler G	1997a	CGA 329351 350 ES (A-9642 C) -Acute dermal toxicity in the rat (limit test). Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Stein, Switzerland, 963151 GLP Syngenta File No CGA329351/0526 (VV-377968)	Y	Y	New study never submitted before to this country	SYN	-
KIIIA1 7.1.4	Winkler G	1997b	CGA 329351 350 ES (A-9642 C) -Acute dermal irritation/corrosion study in the rabbit. Novartis Crop Protection AG, Basel, Switzerland Ciba-Geigy Ltd., Stein, Switzerland, 963152 GLP Syngenta File No CGA329351/0508 (VV-377969)	Y	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 7.1.5	Winkler G	1997c	CGA 329351 350 ES (A-9642 C) -Acute eye irritation/corrosion study in the rabbit. Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Stein, Switzerland, 963153 GLP Syngenta File No A9642C_50002 (VV-510690)	Y	Y	New study never submitted before to this country	SYN	-
KIIIA1 7.1.6	Winkler G	1997d	CGA 329351 350 ES (A-9642 C) – Skin sensitisation test in the Guinea pig -Bühler test. Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Stein, Switzerland, 963154 GLP Syngenta File No CGA329351/0527 (VV-377972)	Y	Y	New study never submitted before to this country	SYN	-
KIIIA1 7.3.2	Marcenac F.	2006	Determination of Operator Exposure to Imidacloprid during Treatment of Sugar Beet Seeds with IMPRIMO in France Syngenta Crop Protection AG, Basel, Switzerland RHODIA Recherches et Technologies, Lab d'Hygiene Industrielle, Saint-Fons, France, 04B033 HI GLP Syngenta File No ASF654/0001 (VV-379857)	N	Y	Submitted for A21172A but no data protection was claimed	SYN	-
KIIIA1 7.6.1	Mewes K.E.	1998	Dermal absorption of [Phenyl-U-14C] CGA 329351 formulated as ridomil Gold 480 EC (A-9408 B) in the rat Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 034AM04 GLP Syngenta File No CGA329351/0865 (VV-377273)	Y	Y	Data Protection started with 2865 on the 27.11.2013; Expiry date 27.11.2023	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 7.6.2	Mewes K.E.	1998a	The in vitro percutaneous absorption of [Phenyl-(U)-14C] CGA 329351 formulated as Ridomil R Gold 480 EC (A-9408B) through rat and human epidermis. Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 34AM05 GLP Syngenta File No CGA329351/0884 (VV-377276)	Y	Y	Data Protection started with 2865 on the 27.11.2013; Expiry date 27.11.2023	SYN	-
IIIA 9.2.1 CP 9.2.1	Wiedemann G.	2014a	Metalaxyl-M - A leaching Assessment for Parent and Three Soil Metabolites Using the FOCUS-PEARL 4.4.4 and FOCUS PELMO 5.5.3 Groundwater Models Following Use as Seed Treatment of Sunflowers Syngenta RIFcon GmbH, Heidelberg, Germany, R1420213-1 Not GLP, not published Syngenta File No CGA329351_11645 (VV-628483)	N	N	-	SYN	-
IIIA 9.2.1 CP 9.2.1	Wiedemann G.	2014b	Metalaxyl-M - A leaching Assessment for Parent and Three Soil Metabolites Using the FOCUS-PEARL 4.4.4 and FOCUS PELMO 5.5.3 Groundwater Models Following Use as Seed Treatment of Spinach Syngenta RIFcon GmbH, Heidelberg, Germany, R1420213-2 Not GLP, not published Syngenta File No CGA329351_11646 (VV-628484)	N	N	N/A	SYN	-
IIIA 9.2.3 CP 9.2.3	Wiedemann	2014c	Metalaxyl-M - A European Environmental Fate Assessment Using FOCUS STEPS1-2 Following Use as Seed Treatment of Sunflowers Syngenta RIFcon GmbH, Heidelberg, Germany, R1420213-5 Not GLP, not published Syngenta File No CGA329351_11649 (VV-628487)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIIA 9.2.3 CP 9.2.3	Wiedemann	2014d	Metalaxyl-M - A European Environmental Fate Assessment Using FOCUS STEPS 1-2 Following Use as Seed Treatment of Spinach Syngenta RIFcon GmbH, Heidelberg, Germany, R1420213-6 Not GLP, not published Syngenta File No CGA329351_11650 (VV-628488)	N	N	N/A	SYN	-
KIIIA1 10.1.2/01 [Evaluated in RAR November 2013]	Schwarz J.	2006	Utilisation of freshly drilled sunflower and maize fields in southern France by birds BASF, Limburgerhof, Germany RIFCON, Leichlingen, Germany, RA06-050-1 2006/1039471 Not GLP, not published Syngenta File No N/1147 (VV-380953)	Y	N	N/A	SYN	-
KIIIA1 10.1.2/02 [Evaluated in RAR November 2013]	Moosmayer P.	2008	Exposure of birds in cereals in Germany in spring - attractiveness of cereal fields, portion of time and diet composition Syngenta - Jealott's Hill, Bracknell, United Kingdom Rifcon, Heidelberg, Germany, RA060006, M-297061-01-1 GLP, not published Syngenta File No NA_11978 (VV-393018)	Y	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	SYN	-
KIIIA1 10.1.2/03 [Evaluated in RAR November 2013]	Render K.	2012	Fludioxinil, Thiabendazole, Azoxystrobin and Metalaxyl-M - Dissipation of residues on treated maize seed and shoots Syngenta - Jealott's Hill, Bracknell, United Kingdom The Food and Environment Research Agency (Fera), Sand Hutton, York, UK. V7YG 1000 GLP, not published Syngenta File No A14918E_10216 (VV-402718)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 10.1.2/04 [Evaluated in RAR November 2013]	Jarratt N.	2012	The uptake of metalaxyl-M from treated seeds into the shoots of emerging seedlings. Syngenta - Jealott's Hill, Bracknell, United Kingdom The Food and Environment Research Agency (Fera), Sand Hutton, York, UK. V7YG 1002 GLP, not published Syngenta File No A9642C_10263 (VV-405158)	N	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.1.3/01 [Evaluated in RAR November 2013]	Johnson A.	1997	CGA 329351, 350 ES (A-9642 C) palatability and dietary toxicity to the Pheasant Novartis Crop Protection AG, Basel, Switzerland Huntingdon Life Sciences Ltd., Huntingdon, United Kingdom, NVR 20/972836 GLP, not published Syngenta File No CGA329351/0682 (VV-377279)	Y	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.1.3/02 [Evaluated in RAR November 2013]	Thompson H. M.	2004a	Untreated seeds: Seed selection by the house sparrow (Passer domesticus) Syngenta Crop Protection AG, Basel, Switzerland Central Science Laboratory, York, United Kingdom, L3EG1003, 2033623 Not GLP, not published Syngenta File No MK936/1043 (VV-340019)	Y	N	N/A	SYN	-
KIIIA1 10.1.3/03 [Evaluated in RAR November 2013]	Thompson H. M.	2004b	Untreated seeds: Seed selection by the grey partridge (Perdix perdix) Syngenta Crop Protection AG, Basel, Switzerland Central Science Laboratory, York, United Kingdom, L3EG1004, 2033623 Not GLP, not published Syngenta File No MK936/1044 (VV-340018)	Y	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 10.2.1/01 [Evaluated in RAR November 2013]	Memmert U.	1997	Acute toxicity of CGA 329351, 350 ES (A-9642 C) to rainbow trout (Oncorhynchus mykiss) in a static test (96 hours) Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, 645208 GLP, not published Syngenta File No CGA329351/0604 (VV-375951)	Y	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.2.1/02 [Evaluated in RAR November 2013]	Memmert U.	1997a	Acute toxicity of CGA 329351, 350 ES (A-9642 C) to Daphnia magna (48 hour immobilization test) Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, 670410 GLP, not published Syngenta File No CGA329351/0726 (VV-376609)	N	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.2.1/03 [Evaluated in RAR November 2013]	Memmert U.	1997b	Toxicity of CGA 329351, 350 ES (A-9642 C) to Scenedesmus subspicatus in an algal growth inhibition test Novartis Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, 645243 GLP, not published Syngenta File No CGA329351/0641 (VV-375954)	N	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.3/01 [Evaluated in RAR November 2013]	Barfknecht R.	2006	Generic Field Monitoring of Mammals in Cereal Fields in Spring and Summer in Germany Bayer Crop Science AG, Monheim, Germany Bayer Crop Science AG, Monheim, Germany, E308 2926-0 M-269779-01-1 GLP, not published Syngenta File No N/1153 (VV-339199)	Y	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 10.3/02 [Evaluated in RAR November 2013]	Barfknecht R	2008	Generic field monitoring of mammals on freshly drilled summer cereals in Hunsruck, Germany Syngenta - Jealott's Hill, Bracknell, United Kingdom Bayer Crop Science AG, Monheim, Germany, BAR/FS038, M295956-01-1 GLP, not published Syngenta File No NA_11977 (VV-393017)	Y	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	SYN	-
KIIA 5.2.1 [From mammalian toxicology section]	Schoch, M.	1994a	Acute oral toxicity in the rat - CGA 329'351. Ciba-Geigy Ltd., Stein Switzerland, Project Report 933179, 06.04.1994 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Syngenta file No: CGA329351/0002 (VV-372570)	Y	Y	New study never submitted before to this country	SYN	-
KIIA 5.6.1 [From mammalian toxicology section]	Cozens, D. et al.	1980	Effect of CGA 48'988 on reproductive function of multiple generations in the rat. Huntingdon Research Centre, UK, Rep. Nr. CBG 181/80254, 13.08.1980 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland. GLP, not published Syngenta file No: CGA48988/0597 (VV-346345)	Y	N	Expired on 10/1/2012	SYN	-
KIIIA1 10.4.1/02 [Evaluated in RAR November 2013]	Kling A.	2012	Metalaxyl-M ES (A9642C) - Acute oral and contact toxicity to the honeybee Apis mellifera L. in the laboratory Syngenta Eurofins Agrosience Services GmbH, Niefern-Öschel., Germany, S11-03400 GLP, not published Syngenta File No A9642C_10040 (VV-401033)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 10.5.1/08 [Evaluated in RAR November 2013]	Candolfi M. P.	1997	A-9642 C (CGA 329351, 350 ES): Laboratory acute toxicity test with the rove beetle, Aleochara bilineata gyllenhal (Coleoptera: staphylinidae) Novartis Crop Protection AG, Basel, Switzerland Springborn Smithers Laboratories, Horn, Switzerland, 97-181-1047 GLP, not published Syngenta File No CGA329351/0580 (VV-377973)	N	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.5.1/09 [Evaluated in RAR November 2013]	Reber B.	1997	Acute toxicity of CGA 329351, ES 350 (A-9642 C) at the ground dwelling predator Poecilus cupreus L. Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 963657 GLP, not published Syngenta File No CGA329351/0589 (VV-377974)	N	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.5.1/10 [Evaluated in RAR November 2013]	Roehlig U.	2011	Metalaxyl-M ES (A9642C) - Chronic Toxicity (ER50) to the Rove Beetle Aleochara bilineata GYLL. Under Extended Laboratory Conditions Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 11 10 48 006 A GLP, not published Syngenta File No A9642C_10039 (VV-397694)	N	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.6.1.2/01 [Evaluated in RAR November 2013]	Friedrich S.	2011	Metalaxyl-M ES (A9642C) - Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 11 10 48 029 S GLP, not published Syngenta File No A9642C_10035 (VV-397000)	N	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.6.2/02 [Evaluated in RAR November 2013]	Friedrich S.	2011a	Metalaxyl-M ES (A9642C) - Effects on the Reproduction of the Collembolans Folsomia candida Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 11 10 48 030 S GLP, not published Syngenta File No A9642C_10037 (VV-397042)	N	Y	New study never submitted before to this country	SYN	-

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	Previously used Y/N If yes, for which data point?
KIIIA1 10.6.2/03 [Evaluated in RAR November 2013]	Vinall S.	2011	Metalaxyl-M (A9642C) - A rate-response laboratory bioassay of the effects of fresh residues on the predatory mite, Hypoaspis aculeifer (Acari, Laelapidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-11-10 GLP, not published Syngenta File No A9642C_10038 (VV-397688)	N	Y	New study never submitted before to this country	SYN	-
CP 1.4.1 KIIIA1 2 / 01	Ravikumar M.	2012	A9651D - Chemical characterization before storage of batch SMO1C756 Syngenta Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMG11109 GLP, not published Syngenta File No A9651D_10087 (VV-400780)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CP 2.8.1 CP 2.8.2 CP 2.8.3 CP 2.8.5.1 CP 2.8.5.3 CP 2.8.7 KIIIA1 2.1 / 01 & KIIIA1 2.8.1 / 01 & KIIIA1 2.8.2 / 01 & KIIIA1 2.8.3.1 / 01 & KIIIA1 2.8.3.2 / 01 & KIIIA1 2.8.5.2 / 01 & KIIIA1 2.8.6.3 / 01 & KIIIA1 2.8.8.1 / 01	Ravikumar M.	2012a	A9651D - Technical properties of batch SMO1C756 Syngenta Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMN10688 Not GLP, not published Syngenta File No A9651D_10089 (VV-400783)	N	N	N/A	SYN	-
CP 2.2 CP 2.3 KIIIA1 2.2.1 / 01 & KIIIA1 2.2.2 / 01 & KIIIA1 2.3.2 / 01 & KIIIA1 2.3.3 / 01	Jackson W.A.	2011	A9651D - Safety study Syngenta Syngenta Technology & Projects, Huddersfield, United Kingdom, HT11/566 GLP, not published Syngenta File No A9651D_10090 (VV-400784)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CP 2.4 CP 2.6 CP 2.8.5.1 CP 2.8.5.2 KIIIA1 2.4.1 / 01 & KIIIA1 2.4.2 / 01 & KIIIA1 2.6.2 / 01 & KIIIA1 2.8.6.1 / 01 & KIIIA1 2.8.6.2 / 01	Ravikumar M.	2012b	A9651D - Physical properties of batch \$MO1C756 Syngenta Syngenta Biosciences Pvt. Ltd., Ilhas Goa, India, SMG11114 GLP, not published Syngenta File No A9651D_10088 (VV-400782)	N	Y	New study never submitted before to this country	SYN	-
CP 2.7 CP 4.4 KIIIA1 2.7.2 KIIIA1 4.1.3 / 01	Kundel P.	2012	A9651D - Storage stability and shelf life statement (8 weeks 40 °C) in packaging made of HDPE Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 10485810 Not GLP, not published Syngenta File No A9651D_10086 (VV-400778)	N	N	N/A	SYN	-
CP 2.7.3 [submitted as additional information during AIR peer review]	Kundel P.	2014	Metalaxyl-M/Mancozeb – A9651D - Storage Stability and Shelf Life Statement (2 Years 20 °C) in Packaging Made of HDPE Summary Report Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, Report No 300016902 Not GLP, not published Syngenta File No. A9651D_10458 (VV-407144)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CP 2.3 KIIIA1 2.3.3 / 01	Bailey M.	2013	Ridomil Gold MZ 68 WG; study nbr : HT-13/013 Syngenta Technology and Engineering, Process hazard Section Huddersfield, West Yorkshire, UK GLP, not published Syngenta File No	N	Y	New study never submitted before to this country	SYN	-
CP 4.2 KIIIA1 4.2.2 / 01	Kundel P.	2012	A9651D - The effectiveness of the spray tank cleaning procedure Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 123796 Not GLP, not published Syngenta File No A9651D_10092 (VV-400785)	N	N	N/A	SYN	-
CP 5.1.1 CP 5.2 KIIIA1 5.2.1 / 01	Schneider B.	1999	Analytical method CGA 329351/ mancozeb in A-9651 D by GLC and Iodometry Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland, AF-1306/4 Not GLP, not published Syngenta File No CGA329351/1100 (VV-125441)	N	N	N/A	SYN	-
CP 5.1.1 CP 5.2 KIIIA1 5.2.1 / 02	Voellmin S.	2012	Statement on validity of method AF-1306/4 for the determination of CGA329351 and CGA351920 by chiral HPLC in formulation A9651D Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 10500223 Not GLP, not published Syngenta File No A9651D_10105 (VV-26504)	N	N	N/A	SYN	-
CP 5.1.1 CP 5.2 KIIIA1 5.2.1 / 03	Schneider B.	1999a	Report on validation of analytical method - AF-1306/4 Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection Münchwilen AG, Münchwilen, Switzerland, 71679 GLP, not published Syngenta File No CGA329351/1129 (VV-292737)	N	Y	New study never submitted before to this country	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
CP 5.1.1 CP 5.2 KIIIA1 5.2.4 / 01	Stampf P.	2001	Analytical Method - 2,6-dimethylaniline in formulation (CGA 72649) in formulation Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection Münchwilen AG, Münchwilen, Switzerland, AG-1837/2 Not GLP, not published Syngenta File No CGA329351/1563 (VV-127870)	N	N	N/A	SYN	-
CP 5.1.1 CP 5.2 KIIIA1 5.2.4 / 02	Stampf P.	2004	Validation of the analytical method AG-1837/2 to analyze 2,6-dimethyl-aniline (CGA72649) in formulations Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, 112691 GLP, not published Syngenta File No A9407A_10000 (VV-382901)	N	Y	New study never submitted before to this country	SYN	-
CP 5.1.1 CP 5.2 KIIIA1 5.2.4 / 03	Voellmin S., Uebelmann P.	2011	Analytical method SD-1489/1 - Determination of GS23201 (Ethylenethiourea) in formulation A9651D Syngenta Syngenta Crop Protection, Münchwilen, Switzerland, SD-1489/1 Not GLP, not published Syngenta File No A9651D_10085 (VV-127970)	N	N	N/A	SYN	-
KIIIA1 7.1.1	Straube E.	2005	Metalaxyl -M and Mancozeb 68 WG Formulation (A9651D) : Acute Oral Toxicity Study in the Rat (Up and Down Procedure) Syngenta Crop Protection AG, Basel, Switzerland RCC - Biological Research Laboratories, Füllinsdorf, Switzerland, RCC 859374 GLP Syngenta File No CGA329351/2095 (VV-378450)	Y	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 7.1.2	Straube E.	2005a	Metalaxyl -M and Mancozeb 68 WG Formulation (A9651D): Acute Dermal Toxicity Study in Rats Syngenta Crop Protection AG, Basel, Switzerland RCC - Biological Research Laboratories, Füllinsdorf, Switzerland, RCC 859375 GLP Syngenta File No CGA329351/2096 (VV-378565)	Y	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 7.1.3	Rattray N	2005	Metalaxyl-M+ Mancozeb 68 WG (A-9651D): 4-Hour Acute Inhalation Toxicity Study In The Rat Syngenta Crop Protection AG, Basel, Switzerland Central Toxicology Laboratory (CTL), Cheshire, United Kingdom, HR2521 GLP Syngenta File No CGA329351/2170 (VV-334989)	Y	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 7.1.4	Kuhn J.	2006	CGA329351-Mancozeb WG (4-64) (A9651D) - Acute Dermal Irritation Study in Rabbits Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 9860-06, T002736-05 GLP Syngenta File No CGA329351/2293 / CGA329351/2290 (VV-335809)	Y	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 7.1.5	Kuhn J.	2006a	CGA329351-Mancozeb WG (4-64) (A9651D) - Acute Eye Irritation Study in Rabbits Syngenta Crop Protection AG, Basel, Switzerland Stillmeadow Inc., Sugarland TX, USA, 9859-06, T002735-05 GLP Syngenta File No CGA329351/2289 (VV-335367)	Y	Y	New study never submitted before to this country	SYN	-
KIIIA1 7.1.6	Arcelin G.	2005	Contact Hypersensitivity in Albino Guinea Pigs, Bühler Test (3-induction) Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, RCC 856575 GLP Syngenta File No CGA329351/2028 (VV-332321)	Y	Y	New study never submitted before to this country	SYN	-
KIIIA1 7.6.1	Mewes K.E.	1998	Dermal absorption of [Phenyl-U-14C] CGA 329351 formulated as ridomilGold 480 EC (A-9408 B) in the rat Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 034AM04 GLP Syngenta File No CGA329351/0865 (VV-377273)	Y	Y	Data Protection started with 2865 on the 27.11.2013; Expiry date 27.11.2023	SYN	-
KIIIA1 7.6.2	Mewes K.E.	1998a	The in vitro percutaneous absorption of [Phenyl-(U)-14C] CGA 329351 formulated as Ridomil R Gold 480 EC (A-9408B) through rat and human epidermis. Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 34AM05 GLP Syngenta File No CGA329351/0884 (VV-377276)	Y	Y	Data Protection started with 3659 on the 13.10.2015; Expiry date 13.10.2025	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
IIIA 9.2.1 CP 9.2.1	Wiedemann G.	2014e	Metalaxyl-M - A leaching Assessment for Parent and Three Soil Metabolites Using the FOCUS-PEARL 4.4.4 and FOCUS PELMO 5.5.3 Groundwater Models Following Use in Tomatoes Syngenta RIFcon GmbH, Heidelberg, Germany, R1420213-3 Not GLP, not published Syngenta File No CGA329351_11647 (VV-628485)	N	N	N/A	SYN	-
IIIA 9.2.1 CP 9.2.1	Wiedemann G.	2014f	Metalaxyl-M - A leaching Assessment for Parent and Three Soil Metabolites Using the FOCUS-PEARL 4.4.4 and FOCUS PELMO 5.5.3 Groundwater Models Following Use in Vines Syngenta RIFcon GmbH, Heidelberg, Germany, R1420213-4 Not GLP, not published Syngenta File No CGA329351_11648 (VV-628486)	N	N	N/A	SYN	-
IIIA 9.2.3 CP 9.2.3	Wiedemann G.	2014g	Metalaxyl-M - A European Environmental Fate Assessment Using FOCUS STEPS1-2 Following Spray Applications to Tomatoes Syngenta RIFcon GmbH, Heidelberg, Germany, R1420213-7 Not GLP, not published Syngenta File No CGA329351_11651 (VV-628489)	N	N	N/A	SYN	-
IIIA 9.2.3 CP 9.2.3	Wiedemann G.	2014h	Metalaxyl-M - A European Environmental Fate Assessment Using FOCUS STEPS 1-2 Following Spray Applications to Vines Syngenta RIFcon GmbH, Heidelberg, Germany, R1420213-8 Not GLP, not published Syngenta File No CGA329351_11652 (VV-628490)	N	N	N/A	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 10.1.1/01 [Evaluated in RAR November 2013]	Gallagher S., Beavers J.	2005	A9651D: An acute oral toxicity study with the northern bobwhite Syngenta Crop Protection AG, Basel, Switzerland Wildlife International Ltd., Easton MD, USA, 528-207 GLP, not published Syngenta File No CGA329351/2154 (VV-378870)	Y	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.2.1/01 [Evaluated in RAR November 2013]	Wheeler J.	2005	Metalaxyl-M/Mancozeb WG (4/64) formulation (A9651D): Acute toxicity to carp (Cyprinus carpio) Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RJ3659B GLP, not published Syngenta File No CGA329351/2147 (VV-378871)	Y	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.2.1/02 [Evaluated in RAR November 2013]	Ashwell J., Watson S., Powley W.	2005	CGA329351 (Metalaxyl-M)/Mancozeb (40/640 g/kg) WG (A9651D): Acute toxicity to the Cladoceran Daphnia magna under static conditions Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, RJ3654B GLP, not published Syngenta File No CGA329351/2141 (VV-333779)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 10.2.1/03 [Evaluated in RAR November 2013]	Maynard S.J.	2005	Metalaxyl-M (CGA329351)/ Mancozeb 4/64 WG formulation (A9651D): Toxicity to the green alga <i>Pseudokirchneriella subcapitata</i> (formerly <i>Selenastrum capricornutum</i>) Syngenta Crop Protection AG, Basel, Switzerland Brixham Environmental Laboratory, Brixham, United Kingdom, BL8150_B GLP, not published Syngenta File No CGA329351/2150 (VV-334059)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIA 5.2.1 [From mammalian toxicology section]	Schoch, M.	1994a	Acute oral toxicity in the rat - CGA 329'351. Ciba-Geigy Ltd., Stein Switzerland, Project Report 933179, 06.04.1994 Owned by Ciba-Geigy Ltd. Basle, Switzerland Submitted by Ciba-Geigy Ltd. Basle, Switzerland GLP, not published Syngenta file No: CGA329351/0002 (VV-372570)	Y	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.4.1/02 [Evaluated in RAR November 2013]	Bocksch S.	2005	CGA329351 / mancozeb (4 / 64) WG Formulation (A9651D): Acute Toxicity to the Honeybee, <i>Apis mellifera</i> L. in the Laboratory Syngenta Crop Protection AG, Basel, Switzerland GAB Biotechnologie GmbH, Niefern, Germany, 20051235/01-BLEU GLP, not published Syngenta File No CGA329351/2151 (VV-334062)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.5.1/08 [Evaluated in RAR November 2013]	Grimm C.	1999	Acute toxicity of CGA 329351, Mancozeb WG 68 (A-9651 D) to the predacious mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 983984 GLP, not published Syngenta File No CGA329351/1086 (VV-308943)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 10.5.1/09 [Evaluated in RAR November 2013]	Hoogendoorn G.	2000	CGA 329351 + mancozeb WG 68 (A-9651 D): A laboratory study to evaluate the effects on the rove beetle, Aleochara bilineata (Coleoptera staphylinidae) Novartis Crop Protection AG, Basel, Switzerland MITOX Consultants, Amsterdam, Netherlands, NO46ABL GLP, not published Syngenta File No CGA329351/1238 (VV-309405)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.5.1/10 [Evaluated in RAR November 2013]	Hoogendoorn G.M.	1999	CGA 329351 + mancozeb WG 68 (A-9651 D): A laboratory study to evaluate the effects on the ground beetle Poecilus cupreus L. (Coleoptera carabidae) Novartis Crop Protection AG, Basel, Switzerland MITOX Consultants, Amsterdam, Netherlands, NO42PCL GLP, not published Syngenta File No CGA329351/1214 (VV-309357)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.5.1/11 [Evaluated in RAR November 2013]	Wientjes J.C.	2000a	Residual effect of 3 rates of CGA 329351 + mancozeb WG 68 (A-9651 D) on the life history of the Green Lacewing, Chrysoperla carnea (Neuroptera: Chrysopidae) determined in a laboratory study Novartis Crop Protection AG, Basel, Switzerland MITOX Consultants, Amsterdam, Netherlands, NO44CCL GLP, not published Syngenta File No CGA329351/1250 (VV-309752)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KIIIA1 10.5.1/12 [Evaluated in RAR November 2013]	Wientjes J.C.	2000b	Residual effect of 3 rates of CGA 329351 + mancozeb WG 68 (A-9651 D) on the life history of the ladybird <i>Coccinella septempunctata</i> determined in a laboratory study Novartis Crop Protection AG, Basel, Switzerland MITOX Consultants, Amsterdam, Netherlands, NO41CSL GLP, not published Syngenta File No CGA329351/1251 (VV-309753)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.5.1/13 [Evaluated in RAR November 2013]	Aldershof S.	1999	Residual effect of 1 application of CGA 329351 (40 g/kg) + mancozeb (640 g/kg) WG 68 (A-9651 D) to the parasitic wasp <i>Aphidius rhopalosiphi</i> (DeStefani-Perez) determined in an extended laboratory study on cereal Novartis Crop Protection AG, Basel, Switzerland MITOX Consultants, Amsterdam, Netherlands, NO43ARE GLP, not published Syngenta File No CGA329351/1215 (VV-312538)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.5.1/14 [Evaluated in RAR November 2013]	Taruza S.	2002	An extended laboratory test to determine the effects of CGA 329351 (40 g/kg) + mancozeb (640 g/kg) WG 68 (A-9651 D) on the ground-dwelling beetle, <i>Aleochara bilineata</i> (Coleoptera: Staphylinidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox. Ltd., Southampton, United Kingdom, NOV-00-9 GLP, not published Syngenta File No CGA329351/1550 (VV-326030)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.5.1/15 [Evaluated in RAR November 2013]	Fallowfield L.	2011	Metalaxyl-M/mancozeb WG (A9651D) - A rate-response extended laboratory bioassay of the effects of fresh residues on the predatory mite, <i>Typhlodromus pyri</i> (Acari: Phytoseiidae) Syngenta Crop Protection AG, Basel, Switzerland Mambo-Tox Ltd., Southampton, United Kingdom, SYN-11-9 GLP, not published Syngenta File No A9651D_10070 (VV-396758)	N	Y	New study never submitted before to this country	SYN	-

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KIIIA1 10.5.1/16 [Evaluated in RAR November 2013]	Grimm C.	2000	Toxicity of CGA 329351 / ASF 21 WG 68 (A-9651 D) to <i>Aphidius rhopalosiph</i> (Hymenoptera: Aphididae) under semi-field conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 2003690 GLP, not published Syngenta File No CGA329351/1422 (VV-312539)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.5.2/01 [Evaluated in RAR November 2013]	Bakker F.M.	1999	Evaluating effects of CGA 329351 / ASF21 WG68 (A-9651 D) applications on predatory mites (Acari: Phytoseiidae) in the field (grape vines, Sth France) Novartis Crop Protection AG, Basel, Switzerland MITOX Consultants, Amsterdam, Netherlands, NO34AFG GLP, not published Syngenta File No CGA329351/1235 (VV-309741)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.5.2/02 [Evaluated in RAR November 2013]	Reber B.	1999	Toxicity of CGA 329351, Mancozeb WG 68 (A-9651 D) to predatory mites (Acari: Phytoseiidae) under field conditions Novartis Crop Protection AG, Basel, Switzerland Novartis Crop Protection AG, Basel, Switzerland, 983951 GLP, not published Syngenta File No CGA329351/1206 (VV-309731)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.5.2/03 [Evaluated in RAR November 2013]	Muether-Paul J.	2009	Metalaxyl-M/Mancozeb WG (A9651D): A Field Study to Evaluate the Effects of A9651D on Predatory Mites (Acari: Phytoseiidae) in a Vineyard in Germany Syngenta Crop Protection AG, Basel, Switzerland Eurofins - GAB, Niefern Öschelbronn, Germany, S09-01790 GLP, not published Syngenta File No A9651D_10042 (VV-386196)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-

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KIIIA1 10.6.1.1/01 [Evaluated in RAR November 2013]	Schmidt T.	2005	CGA329351/Mancozeb WG (4/64) (A95651D): Acute Toxicity of a 4%/64% WG Formulation to the Earthworm Eisenia Fetida in a 14 Day Test in Artificial Soil Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, A21688 GLP, not published Syngenta File No CGA329351/2153 (VV-334206)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-
KIIIA1 10.6.1.2/02 [Evaluated in RAR November 2013]	Friedrich S.	2007	CGA329351/mancozeb WG (4/64) (A9651D) - Sublethal toxicity to the earthworm Eisenia fetida Syngenta Crop Protection AG, Basel, Switzerland BioChem agrar, Gerichshain, Germany, 07 10 48 002 S GLP, not published Syngenta File No CGA329351/2397 (VV-337989)	N	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.6.2/04 [Evaluated in RAR November 2013]	Friedrich S.	2011	Metalaxyl-M/mancozeb WG (A9651D) - Effects on the reproduction of the Collembolans Folsomia candida Syngenta Crop Protection AG, Basel, Switzerland BioChem Agrar, Gerichshain, Germany, 10 10 48 032 S GLP, not published Syngenta File No A9651D_10075 (VV-397044)	N	Y	New study never submitted before to this country	SYN	-
KIIIA1 10.7.1/01 [Evaluated in RAR November 2013]	Voelkel W.	2005	Determination of effects of A9651D on soil microflora activity Syngenta Crop Protection AG, Basel, Switzerland RCC Ltd., Itingen, Switzerland, 858682 GLP, not published Syngenta File No CGA329351/2127 (VV-333793)	N	Y	Data Protection started with Pfl.Reg.Nr. 2760 on 21.04.2015; Expiry date 21.04.2025	SYN	-

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	Previously used Y/N If yes, for which data point?
KIIIA1 10.6/01 [Evaluated in RAR November 2013]	Waelder L.	2001	Herbicide profiling test to evaluate the phytotoxicity of CGA 329351 / ASF 21 68WG (A-9651 D) to terrestrial non-target higher plants Syngenta Crop Protection AG, Basel, Switzerland Syngenta Crop Protection AG, Stein, Switzerland, 50 Not GLP, not published Syngenta File No CGA329351/1457 (VV-311108)	N	N	N/A	SYN	-

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

Syngenta is not the notifier for approval of the active substance oxathiapiprolin and appropriate letters of access are included in this submission. Syngenta reached agreement with the data owner to access the studies necessary for this evaluation. Only the studies that are relevant for the registration of the product Orondis VIP are listed. Please, refer to the data owner for further details.

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	Previously used Y/N If yes, for which data point?
KCA2 6.3.5	Spence, C. Brown, D.	2011/12	Decline and magnitude of residues of DPX-QGU42 and its metabolites in field lettuce (leafy vegetables) following foliar application of DPX-QGU42 100 g/L OD or DPX-QGU42 100 g/L SE – Europe, 2011-2012. Report No 696296, document No Dupont-31734. GLP Not published	N	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	Corteva (SYN LoA)	N/R, Please refer to data owner
KCA2 6.3.7	Spence, C. Brown, D.	2015	Decline and magnitude of residues of DPX-QGU42 and its metabolites in dry bulb onions (Bulb vegetables) following foliar application of DPX-QGU42 100 g/L OD or DPX-QGU42 100 g/L SE - Europe 2012-2013 Report No. DuPont - 31988 GLP Not published	N	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	Corteva (SYN LoA)	N/R, Please refer to data owner
KCA2 6.5.2	Spence, C. Woodmansey, L.	2012	Magnitude of residues of DPX-QGU42 and its metabolites in processed commodities of grapes following application of DPX-QGU42 100 g/L OD - Europe, 2010-2011. Charles River Laboratories (UK) DuPont-30045, Charles River Study Number 695753 GLP Not published	N	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	Corteva (SYN LoA)	N/R, Please refer to data owner
KCA2 6.5.2	Shepard, E.	2012a	Magnitude of residues of DPX-QGU42 and its metabolites in processed commodities of tomato following applications of DPX-QGU42 100 g/L OD and DPX-QGU42 200 g/L SC at an exaggerated rate - USA and Canada, 2011. ABC Laboratories, Inc. (Missouri) Report No. DuPont-31728, MRID 49011239 GLP Not Published	N	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	Corteva (SYN LoA)	N/R, Please refer to data owner

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	Previously used Y/N If yes, for which data point?
KCA2 6.5.3	Spence, C. Brown, D.	2015	Decline and magnitude of residues of DPX-QGU42 and its metabolites in dry bulb onions (Bulb vegetables) following foliar application of DPX-QGU42 100 g/L OD or DPX-QGU42 100 g/L SE - Europe 2012-2013, Report No. Dupont-31988. GLP Not published	N	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	Corteva (SYN LoA)	N/R, Please refer to data owner

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.4	Toth-Gonczol, K.	14/10/2020	Metalaxyl-M / Oxathiapiprolin DC (A23109A) – In Vitro Skin Irritation Test in the EPISKIN™ Model Report No. 20/131-043B Document No. VV-876289 Test Facility Charles River Laboratories Hungary, Kft. GLP Unpublished	N	Y	study report never submitted before to Poland	SYN

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
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