

DRAFT REGISTRATION REPORT

Part A

Risk Management

Product code: A9873C

Product name: WAKIL XL

Chemical active substances:

Cymoxanil, 100 g/kg

Fludioxonil, 50 g/kg

Metalaxyl-M, 169.6 g/kg

~~United Kingdom~~

Great Britain (GB)

NATIONAL ASSESSMENT

~~(Renewal of authorisation)~~

Submitted to support Article 7 amendment of approval of
Metalaxyl-M in GB

Applicant: Syngenta

Submission date: 21/10/2021

Finalisation date : 31/01/2024

Version history

When	What
October 2021	Applicant submission to support amendment of approval under Article 7 of retained Regulation (EC) No 1107/2009
December 2023	HSE (GB) assessment added in green boxes

This is an application from Syngenta for the renewal of WAKIL XL (A9873C) under Article 43 of Regulation (EC) No. 1107/2009 following the renewal of EU approval of the active substance metalaxyl-M.

No equivalence assessment is required.

This application follows the data requirements for the active substance laid down in Regulation (EU) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EU) No. 545/2011, also called ‘old’ data requirements. Metalaxyl-M is an ‘AIR-2’ substance which approval has been renewed in accordance with Regulation (EU) No 1141/2010, therefore Regulations (EU) No 283/2013 and (EU) No 284/2013 are not applicable to the renewal of authorizations for metalaxyl-M-containing plant protection products (derogation by Commission Regulation (EU) No 2015/1475; further details in the guidance document SANTE/11509/2013 rev. 5.2).

Following the renewal of EU approval of the active substance metalaxyl-M, the submission for the product renewal of WAKIL XL (A9873C) was made by 01 September 2020, in accordance with Article 43 of Regulation (EC) No 1107/2009.

All data relied on are provided with this application. The reference lists at Appendix 1 of dRR Part B Sections 1-10 define the data owner and data access. Data protection is a national concern and is addressed in Part A, Appendix 4.

The guidance on Renewal of Authorization according to Art 43 (SANCO/2010/13170 rev 14) requests that within the dRR ‘changes to the risk assessment are highlighted’. This is the first submission of WAKIL XL (A9873C) in the dRR format of April 2015, consequently all of the summary text is previously unreviewed and should be considered as ‘changed’. To facilitate the review, Syngenta has highlighted the summaries of reports not previously reviewed by the zRMS in yellow.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	<p>The applicant, Syngenta Crop Protection AG, submitted this application to amend the conditions of approval of metalaxyl-M in accordance to Article 7 of Regulation 1107/2009 in Great Britain (GB).</p> <p>On the 5 May 2020 the Commission Implementing Regulation (EU) 2020/617 renewing the approval of the active substance metalaxyl-M, and restricting the use of seed treated with a plant protection product containing it to be sown only in greenhouses, was published¹. The renewal of metalaxyl-M applies since 1 June 2020. Since this was before</p>

¹ Commission Implementing Regulation (EU) 2020/617 of 5 May 2020 renewing the approval of the active substance metalaxyl-M, and restricting the use of seeds treated with plant protection products containing it, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of

UK withdrawal from the EU, the Commission Implementing Regulation for the renewal of metalaxyl-M applies direct in GB.

Two representative formulations were considered in the renewal of approval for metalaxyl-M, 'Apron XL' (A9642C) and 'Ridomil Gold Mz'/68 WG Fubol Gold' (A9651D). For this Article 7 amendment application in GB, two different formulations have been considered. The formulation 'Vibrance SB' (A20607B) containing 14.4 g/L metalaxyl-M, 22.5 g/L fludioxonil and 15.0g/L sedaxane to support the field seed treatment use on sugar and fodder beet, and the formulation 'Wakil XL' (A9873C) containing 169.6 g/Kg metalaxyl-M, 100 g/Kg cymoxanil and 50 g/Kg fludioxonil to support the field seed treatment use on peas (vining) are the basis of this Article 7 application for metalaxyl-M to GB.

The applicant has re-submitted the draft registration reports prepared for the product renewals of 'Vibrance SB' and 'Wakil XL' under Article 43 of Regulation No 1107/2009 following the renewal of approval of the active substance metalaxyl-M. The information and data submitted within these draft registration reports have been considered previously by HSE for the applications for authorisation of a new product under Article 33 of Regulation No 1107/2009. Where relevant, re-evaluation of data or information has not occurred where studies have been performed in accordance with the current requirements and the results have been deemed acceptable.

This draft registration report has been provided by the applicant, where required, comments have been inserted in green boxes by HSE or the text amended by the HSE in green (applicant's text has been struck through in green where necessary).

HSE notes that the product authorisations for 'Vibrance SB' and 'Wakil XL' were withdrawn in GB by the applicant. This was based on the approval restriction provided for in Commission Implementing Regulation (EU) 2020/617 that only the treatment of seeds intended to be sown in greenhouses may be authorised. Since all authorised GB uses of 'Vibrance SB' and 'Wakil XL' products are on seeds which are direct drilled in the field, these products do not comply with the restriction and therefore could not be renewed under Article 43 of Regulation No 1107/2009. HSE notes that no authorisation for 'Vibrance SB' or 'Wakil XL' is sought within this Article 7 amendment application. Therefore, HSE has only considered the information presented in the draft registration reports that relate to metalaxyl-M. For a future GB authorisation of these products a separate application would be required with a full evaluation of the data and information for all active substances present in the formulation.

Note that as of 1st January 2024, The Retained EU Law (Revocation and Reform) Act 2023 has taken effect and retained EU law are now known as assimilated law. As this assessment has been prepared prior to the Retained EU Law Act taking effect, assessment may still refer to "retained" regulation as opposed to "assimilated".

Table of Contents

1	Details of the application	6
1.1	Application background	6
1.2	Letters of Access	6
1.3	Justification for submission of tests and studies	6
1.4	Data protection claims	6
2	Details of the authorization decision	8
2.1	Product identity	8
2.2	Conclusion	8
2.3	Substances of concern for national monitoring	8
2.4	Classification and labelling	8
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	8
2.4.2	Standard phrases under Regulation (EU) No 547/2011	10
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	10
2.5	Risk management	10
2.5.1	Restrictions linked to the PPP	10
2.5.2	Specific restrictions linked to the intended uses	11
2.6	Intended uses (only NATIONAL GAP)	12
3	Background of authorization decision and risk management	14
3.1	Physical and chemical properties (Part B, Section 2)	14
3.2	Efficacy (Part B, Section 3)	17
3.3	Efficacy data	17
3.3.1	Information on the occurrence or possible occurrence of the development of resistance	17
3.3.2	Adverse effects on treated crops	18
3.3.3	Observations on other undesirable or unintended side-effects	18
3.4	Methods of analysis (Part B, Section 5)	19
3.4.1	Analytical method for the formulation	20
3.4.2	Analytical methods for residues	20
3.5	Mammalian toxicology (Part B, Section 6)	21
3.5.1	Acute toxicity	23
3.5.2	Operator exposure	24
3.5.3	Worker exposure	26
3.5.4	Bystander and resident exposure	27
3.6	Residues and consumer exposure (Part B, Section 7)	29
3.6.1	Residues	30
3.6.2	Consumer exposure	32
	Combined exposure and risk assessment	33
	Chronic consumer risk assessment from combined exposure	33
	Acute consumer risk assessment from combined exposure	34
3.7	Environmental fate and behaviour (Part B, Section 8)	35
3.7.1	Predicted environmental concentrations in soil (PEC _{soil})	36
3.7.2	Predicted environmental concentrations in groundwater (PEC _{gw})	38

3.7.3	Predicted environmental concentrations in surface water (PEC _{sw}).....	40
3.7.4	Predicted environmental concentrations in air (PEC _{air}).....	42
3.8	Ecotoxicology (Part B, Section 9)	43
3.8.1	Effects on terrestrial vertebrates	43
3.8.2	Effects on aquatic species	44
3.8.3	Effects on bees	44
3.8.4	Effects on other arthropod species other than bees.....	44
3.8.5	Effects on soil organisms	44
3.8.6	Effects on non-target terrestrial plants	45
3.8.7	Effects on other terrestrial organisms (Flora and Fauna).....	45
3.9	Relevance of metabolites (Part B, Section 10)	46
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	49
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization	50
Appendix 1	Copy of the product authorization	51
Appendix 2	Copy of the product label	52
Appendix 3	Letter of Access	53
Appendix 4	Lists of data considered for national authorization.....	54

PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Syngenta for a national renewal.

The application was for approval of WAKIL XL (A9873C), a WG formulation containing 100 g/kg cy-moxanil, 50 g/kg fludioxonil and 169.6 g/kg metalaxyl-M for use as a fungicide seed treatment on diverse crops (see details of intended uses on paragraph 2.6 of this document).

To obtain renewal of authorization the product A9873C, must (where appropriate) meet the conditions of active substance EU inclusion and be supported by a dossier satisfying the requirements of Commission Regulation (EU) No. 545/2011.

The application was submitted in order to allow the renewal of authorization of this product/uses in the concerned Member States 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:

There is no repetition of studies involving vertebrates. Animal studies were only performed where there were no data available to address an endpoint, no extrapolation to existing data possible or the available data were not done according to modern guidelines. 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:

Since this product was previously registered there have been changes to active substance endpoints and test, study and assessment guidelines; therefore where necessary in order to obtain re-approval new tests and study reports are provided.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of A9873C, in accordance with Article 59 of Regulation (EC) No. 1107/2009, it is indicated in **Appendix 4** of this document.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	Studies in which data protection is claimed is present in the DAR Vol 2. For new studies relied upon, data will get standard protection line with assimilated regulation (EC) 1107/2009.

2 Details of the authorization decision

2.1 Product identity

Product code	A9873C
Product name in MS	WAKIL XL
Authorization number	MAPP 17217
Function	Fungicide
Applicant	Syngenta UK Ltd.
Active substance(s) (incl. content)	Cymoxanil; 100 g/kg Fludioxonil, 50 g/kg Metalaxyl-M; 169.6 g/kg
Formulation type	Water dispersible granules [WG]
Packaging	Professional user 1 - 10 kg HDPE canister 300 kg Polyethylene lined polypropylene flexible pack container
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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	Please refer to HSE DAR Volume 1 for details on the conclusions for this application for amendment of the approval of metalaxyl-M in GB.

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:	Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure, Category 2
-------------------------------	---

	Chronic aquatic toxicity, Category 1
--	--------------------------------------

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:	  GHS09; GHS08
Signal word:	Warning
Hazard statement(s):	H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child. H373: May cause damage to organs through prolonged or repeated exposure H410: Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	Prevention: P201 Obtain special instructions before use. P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention. Disposal: P391 Collect spillage.
Additional labelling phrases:	To avoid risks to human health and the environment, comply with the instructions for use. [EUH401]
	Contains cymoxanil. May produce an allergic reaction. [EUH208]
	Hazardous components which must be listed on the label: 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains cymoxanil. May produce an allergic reaction.
	Hazardous components which must be listed on the label: 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	<u>Toxicology:</u> Based on the information available, the formulated product A9873C meets the criteria for classification for the following human health hazard in accordance with Regulation 1272/2008 (CLP): Reproductive toxicity Category 2 (Fertility and Development) (H361fd) Specific Target Organ Toxicity- Repeat Exposure Category 2 (H373)

The following label elements should be used with respect to human health:	
Hazard class(es), categories	Repro. Cat. 2, H361fd STOT-RE Cat. 2 H373
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS08
Signal word	Warning
Hazard statement(s)	Suspected of damaging fertility. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.
Precautionary Statements triggered by human health hazard classification	
P280 Wear protective gloves/protective clothing/eye protection/face protection P308 + P313 IF exposed or concerned: Get medical advice/attention. P314: Get medical advice/ attention if you feel unwell.	
EUH208	'Contains Cymoxanil. May produce an allergic reaction'
In addition to the human health hazard classifications, the label needs to include the additional labelling EUH208 'Contains Cymoxanil. May produce an allergic reaction'.	
No other classification for human health hazards is required based on the submitted information and in accordance with Regulation 1272/2008.	

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).
------	---

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

	Refer to national product label
--	---------------------------------

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:

None	Gloves for the calibration, mixing/loading and cleaning tasks.
Worker protection:	
None	Gloves while loading hopper.
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)

PPP (product name/code):	WAKIL XL / A9873C	Formulation type:	WG ^(a, b)
Active substance 1:	Cymoxanil	Conc. of a.s. 1:	100 g/kg ^(c)
Active substance 2:	Fludioxonil	Conc. of a.s. 2:	50 g/kg ^(c)
Active substance 3:	Metalaxyl-M	Conc. of a.s. 3:	169.6 g/kg ^(c)
Safener:	safener	Conc. of safener:	n/a ^(c)
Synergist:	synergist	Conc. of synergist:	n/a ^(c)
Applicant:	Syngenta	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Interzonal ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes/no		
Field of use:	Fungicide		

GAP rev. , date: 2020-09-01

Use- No.	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g safener/synergist per ha	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	g product / 100 kgs seeds	g a.s./100kg seeds 1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	g a.s./ha 1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	Slurry volume mL/100 kg min / max			
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)															
Minor uses according to Article 51 (interzonal uses)															
15	UK	Combining peas [PIBSS]	I	<i>Peronospora viciae</i> , <i>Ascochyta complex</i> : <i>Ascochyta pisi</i> , <i>Myco- sphaerella pinodes</i> , <i>Phoma medicaginis</i> var. <i>Pinodella</i> , <i>Pythium spp.</i>	Seed treatment	BBCH 00	1	n/a	200	1) 33.9 2) 20 3) 10	1) 67.8 2) 40 3) 20	3500	n/a	Seeding rate maxi- mum 200 kg seeds/ha TGW: 250 g Use: Field Varieties of com- mon pea (<i>Pisum sativum</i>) harvested when fully mature	
			F		Sowing	BBCH 00									
			n.a.		Trans- planting	n.a.									

Use- No.	Member state(s)	Crop and/ or situation (crop destina- tion / purpose of crop)	F G or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate				PHI (days)	Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	g product / 100 kgs seeds	g a.s./100kg seeds 1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	g a.s./ha 1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	Slurry volume mL/100 kg min / max		
17	UK	Vining peas [PIBSS]	I	<i>Peronospora viciae</i> , <i>Ascochyta complex</i> : <i>Ascochyta pisi</i> , <i>Mycosphaerella pinodes</i> , <i>Phoma medicaginis</i> var. <i>pinodella</i> <i>Pythium spp.</i> ,	Seed treatment	BBCH 00	1	n/a	200 g prod- uct/ 100 kgs seeds Or <i>40 g prod- uct/100 000 seeds</i>	1) 33.9/ 30.15 2) 20/ 17.78 3) 10/ 8.89	1) 76.3/ 67.8 2) 45/ 40 3) 22.5/ 20	3500	n/a	Seeding rate: maxi- mum 225 kg seeds/ha TGW:min 225 g Use: Field Varieties of com- mon pea (<i>Pisum sativum</i>) harvested green for canning, freezing or market- ing fresh. <i>Seeding density: 1000000 seeds/ha</i>
			F		Sowing	BBCH 00								
			n.a.		Trans- planting	n.a.								

Please note: Blue colour font - Alternative dose expression

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

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.

(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.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	<p>'Wakil XL' was not the representative product for the approval of metalaxyl-M. 'Wakil XL' has been assessed in the current evaluation as a representative product for the Article 7 amendment to the approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Wakil XL' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.</p> <p>The information presented below has been provided by the applicant, where required, comments have been inserted in green boxes by HSE or the text amended by the HSE in green (applicant's text has been struck through in green where necessary).</p> <p>'Wakil XL' is a WG formulation containing 169.6 g/kg metalaxyl-M, 100 g/kg cymoxanil and 50 g/kg fludioxonil.</p> <p>The intended in-use concentration of product is 11.4% to 54%. It is not noted on what basis this means, i.e. w/v or v/v. As the product is not to be authorised, and as such has no proposed label, the studies have not been strictly evaluated in relation to the in use concentration – this may be revisited for a future product authorisation.</p> <p>All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable (studies previously evaluated have not been reopened). 'Wakil XL' is a red solid. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of $214 \pm 5^{\circ}\text{C}$. The pH of the 1% dilution of the preparation is 6.0.</p> <p>Acceptable physical, chemical and technical data have been provided indicating that the product fulfils the requirements of a WG formulation.</p> <p>Acceptable accelerated (2 weeks at 54°C, and others) storage stability data have been submitted indicating the product does retain its technical properties during storage. Data on the content of metalaxyl-M, cymoxanil and fludioxonil before and after accelerated storage shows no significant degradation.</p> <p>The content of the relevant impurities CGA72649, CGA363736 and CGA226048 have not been determined pre- or post- storage. The applicant submitted a case with regards to the inability for the metabolites to form on storage for a similar application containing metalaxyl-M. The applicants case for CGA72649 and CGA 363736 was accepted. The applicants case with regards to CGA226048 was not accepted, HSE is of the view that there is potential for CGA226048 to form on storage, see data requirements below. However, as this article 7 seeks to remove the classification of CGA226048 as a relevant impurity, no further information will be requested at this time. This may be reopened for future applications if it is decided that the metabolite is to remain relevant. Additionally, the applicants case with respect to the potential (or lack thereof) for formation of CGA72649 and CGA 363736 on storage was accepted on the basis of the composition of 'Wakil XL', this case may not be accepted for future products.</p> <p>A low temperature storage stability data is not required and has not been submitted.</p> <p>An ambient shelf-life study has been submitted, conducted using product stored in HDPE, propyl-</p>

ene, Box with inner bag (paper/PE/PVDC), Packaging material: Box with inner bag (paper/PE/Al), bag made of PE. The data indicate the product does retain its technical properties during storage. Data on the content of metalaxyl-M, cymoxonil and fludioxonil before and after ambient storage shows no significant degradation. As above, the content of the relevant impurities was not determined pre- or post-storage. A shelf life of at least 2 years at ambient temperature when stored in HDPE, propylene, box with inner bag (paper/PE/PVDC), box with inner bag (paper/PE/Al), bag made of PE is supported.

Tank Mixing

No product label has been included in the evaluation of the Article 7, as the representative products will not be authorised.

Compliance with FAO specifications:

A FAO specification for metalaxyl-M is not available

Formulation used for tests

The preparation used in the tests was "A9873C" batch P.805004, KWL8J039 or KWL0K111. This is the same composition as the proposed product "A9873C"

Conclusion:

Sufficient data on physical and chemical properties are available for the plant protection product. It is noted that the product is not to be authorised for use on the back of this evaluation. In addition, only metalaxyl-M has been considered in detail, for a future product authorisation, the decision on the acceptability of the data may be revisited. A number of points of consideration have been noted in table 2-1.

WAKIL XL (A9873C) is a water dispersible granules (WG) formulation for seed treatment. 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 red solid with a weak odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of 214 °C. In aqueous solution, it has a pH value around 6.0. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a WG formulation.

The intended concentration of use is 11.4% to 57%.

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 A9873C.

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 A9873C.

Compliance with FAO specifications:

There is no FAO specification for A9873C.

Formulation used for tests:

All physico-chemical endpoints were measured using A9873C. Thus, no bridging to other formulations is required.

3.2 Efficacy (Part B, Section 3)

WAKIL XL (A9873C) is a water dispersible granule formulation containing 169.6 g/kg metalaxyl-M, 100 g/kg cymoxanil and 50 g/kg fludioxonil for use as a seed treatment for the control of downy mildew (*Peronospora viciae*), Ascochyta complex (*Ascochyta sp.*, *Mycosphaerella pinodes* and *Phoma medicaginis*), *Botrytis cinerea*, *Pythium spp.* and *Fusarium spp.* in combining and vining peas.

3.3 Efficacy data

There has been no GAP change that impacts the previous Efficacy evaluation of A9873C. Therefore, no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, *Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009*.

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

Metalaxyl-M

Metalaxyl-M inhibits protein synthesis in fungi by interference with the synthesis of ribosomal RNA. It is a systemic fungicide with protective and curative action and is taken up by leaves stems and roots. Metalaxyl-M belongs to the phenylamides (PAs) which are a highly active class of fungicides specifically controlling plant pathogens belonging to the Oomycetes (the downy mildews of the Peronosporales and Sclerosporales, as well as most members of the Pythiales (e.g. *Phytophthora* and *Pythium spp.*) and Saprolegniales. Phenylamide fungicides are in commercial use since 1978.

Metalaxyl-M penetrates the plant tissue rapidly, is translocated acropetally within the plant and as all PAs inhibits rRNA biosynthesis (polymerase complex I) in the target pathogens. Resistance towards phenylamides and cross resistance is well known in various oomycetes, especially with *Phytophthora infestans* and *Peronospora spp.*. FRAC characterizes the risk for resistance development as high, because of the single site mode of action.

Cymoxanil

Cymoxanil belongs to the chemical class of the cyanoacetamide-oximes. It is a protective and curative fungicide with special activity against oomycete pathogens. It has a short persistence in plant tissue only. The primary inhibitory effect of cymoxanil in the cells is not known, but since sensitive strains metabolise it, in contrast to resistant strains, suggests that it may be a pro-fungicide.

The fungicide risk for resistance development is considered by FRAC as low to medium for cyanoacetamideoximes. Resistance is reported for *Plasmopara viticola* in grapevines only (Italy), probably caused by repeated applications for curative action.

Fludioxonil

Fludioxonil is a non-systemic phenylpyrrol based chemistry derived from the natural product pyrrolnitrin. It has a broad range of activity within the ascomycetes and basidiomycetes. The primary effect of fludioxonil is the inhibition of spore germination after preventative application. The mechanism of action is not fully resolved, however, histidine kinase (Os-2 MAP kinase) involved in osmose is inhibited and mutations in the corresponding HOG1 gene mediate resistance to phenylpyrroles. Possibly additional genes or mechanisms are involved.

Fludioxonil is a single site inhibitor but this molecule affects a signaling cascade. The mechanism of resistance is not fully resolved, however, mutations in the histidine kinase (Os-2 MAP kinase) involved in osmosensing can mediate resistance to phenylpyrroles in some pathogens as well as mutations in the upstream osmosensor Os-1 histidine kinase which is the suspected target. Possibly also additional genes or mechanisms are involved, since in *Botrytis cinerea* inheritance studies enabled to propose one major gene, but also slightly deviating segregation patterns could be observed suggesting alternative mechanisms are involved.

Phenylpyrroles are not cross resistant to any other fungicide classes, like anilopyrimidines, MBC, QoI, DMI or SDHI. In *Botrytis cinerea*, mutations in the Os1 genes which confer strong resistance towards Fludioxonil can be generated in the lab but these are very infrequent in the field. This is likely because mutations in the osmosensing MAP kinase pathway are frequently associated with a strong fitness penalty (increased osmosensitivity, inability for infection in planta). Resistance mechanism leading to low / moderate resistance levels were found in relation to the de-regulated expression of a transporter gene (detoxification mechanism). This is achieved but the accumulation of mutations in a transcription factor termed Mrr1 (██████████ et al., 2009; ██████████ et al., 2012).

The fungicide risk is considered by EPPO and FRAC as medium for phenylpyrroles

3.3.2 Adverse effects on treated crops

There has been no GAP change that impacts the previous Efficacy evaluation of A9873C. Therefore, no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, *Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009*.

3.3.3 Observations on other undesirable or unintended side-effects

There has been no GAP change that impacts the previous Efficacy evaluation of A9873C. Therefore, no new information is provided under this point in accordance with SANCO/2010/13170 rev. 14, 7 October 2016, *Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009*.

3.4 Methods of analysis (Part B, Section 5)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD)
Reviewer's comments	<p>'Wakil XL' was not the representative product for the approval of metalaxyl-M. 'Wakil XL' has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Wakil XL' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.</p> <p>'Wakil XL' is a WG formulation containing 169.6 g/kg metalaxyl-M, 100 g/kg cymoxanil and 50 g/kg fludioxonil. The proposed uses considered under this application are for fresh peas.</p> <p>The applicant company has access to the data considered in the DAR/RAR for metalaxyl-M as they are the data owner.</p> <p>This evaluation has been carried out in accordance with the Uniform Principles (as defined in Article 29 of Regulation (EC) No. 1107/2009) for active substance and product evaluation concerning the placing of plant protection products on the market. The renewal of 'metalaxyl-M' was assessed in accordance with the data requirements outlined in Regulation (No) 544/2011. Therefore, as methods of analysis data is considered active substance data, in accordance with the guidance document SANTE/11509 /2013– rev. 5.2 this methods assessment has been conducted in accordance with the same data requirements applied to the active.</p> <p>The information presented below in has been written by the applicant, where required, comments have been inserted in green boxes by the HSE or the text amended by the HSE in green (applicant's text has been struck through in green where necessary).</p> <p>Sufficiently validated analytical methods are available for:</p> <ul style="list-style-type: none"> the active substance, metalaxyl-M in the plant protection product the relevant impurities: CGA72649, CGA363736 in the plant protection product; methods are not available for CGA226048, however the current application seeks to remove CGA226048 as a relevant impurity in the current GB approval, therefore this has not been considered further, depending on the outcome of the Art 7 application, methods may be required for CGA226048 for a future authorisation <p>New data generation methods in support of support of efficacy, environmental fate, residues in plants, residues in animal products, toxicology and ecotoxicology studies were not submitted and are not required.</p> <p>Sufficiently validated analytical methods are available to allow monitoring of residues of metalaxyl-M in</p> <ul style="list-style-type: none"> plants in all crop groups (further data was submitted but not evaluated or required) animal matrices (further data was submitted but not evaluated or required) soil, water, and air body fluids and tissues

Conclusion:

Sufficiently sensitive and selective analytical methods are available to support the plant protection product for the proposed uses.

3.4.1 Analytical method for the formulation

An analytical method has been developed for the determination of Cymoxanil, Fludioxonil and Metalaxyl-M (including its S-enantiomer) in plant protection product A9873C. Full validation of the method AF-1318/2 has been conducted. The method is suitable for the specific, accurate and precise determination of Metalaxyl-M (CGA329351) and its S-enantiomer (CGA351920) in plant protection product Wakil XL (A9873C).

Fludioxonil and cymoxanil do not contain any impurity of toxicological or ecotoxicological concern. Metalaxyl-M contains the relevant impurities CGA72649 and CGA363736.

CGA72649 and CGA363736 in Metalaxyl-M

Analytical method SD-1751/1 has been developed and fully validated for the determination of the relevant impurity CGA72649 and CGA363736 in A9873C. The method is suitable for the specific, accurate and precise determination of CGA72649 and CGA363736 in product A9873C.

There are no relevant formulants in A9873C therefore no methods are required.

There are no CIPAC methods for the determination of Cymoxanil, Fludioxonil and Metalaxyl-M in WG formulations.

3.4.2 Analytical methods for residues

Pre- and post-authorisation analytical methods for Cymoxanil, Fludioxonil and Metalaxyl-M 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.

3.5 Mammalian toxicology (Part B, Section 6)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY						
Name of authority	HSE Chemicals Regulation Division (CRD), UK					
Reviewer's comments	<u>Toxicology:</u>					
	<i>Human health hazard assessment</i>					
	The applicant proposes to meet the data requirements for acute toxicity (oral, dermal), skin and eye irritation and skin sensitisation using studies previously evaluated by HSE. The studies were accepted and evaluated during the following zonal application. Summaries of the studies and confirmation of the conclusions from their evaluation can be found in Appendix 2 of the dRR B6. For acute inhalation toxicity, no data has been provided, the applicant has produced a waiver for generating data. HSE concludes that the waiver is acceptable (see Appendix 2 of dRR B6 for details).					
	Based on the information available, the formulated product A9873C does not meet the criteria for classification for any acute human health hazard in accordance with Regulation 1272/2008 (CLP).					
	The product contains the active cymoxanil. Cymoxanil is classified in Category 2 for reproductive toxicity (developmental and fertility) and specific target organ toxicity- repeat exposure in accordance with the GB MCL. Cymoxanil is present at 100 g/L or 10 % w/w in the product. In accordance with Regulation 1272/2008 (CLP), the generic concentration limits are ≥ 3% and ≥ 10%, respectively; therefore the product should be classified for Repro. Cat. 2, H361fd and STOT-RE Cat. 2 H373.					
	<i>Reference Values</i>					
	The agreed toxicological reference values for metalaxyl-M are as follows:					
	<u>Metalaxyl-M (17% in product) (EFSA Journal 2015;13(3):3999)</u>					
	Classification	Acute oral toxicity Category 4; H302, Serious eye damage Category 1; H318; EU CLH and GB MCL (mandatory classification)'				
	AOEL	0.08 mg/kg bw/d	NOAEL = 8 mg/kg bw/d	AF= 100	Dog RDT studies (90-day, 6-month, 1 &2-years)	Increases in liver weight and AP and ALT levels; anaemia
	ADI	0.08 mg/kg bw/d	NOAEL = 8 mg/kg bw/d	AF= 100	Dog RDT studies (90-day, 6-month, 1 &2-years)	Increases in liver weight and AP and ALT levels; anaemia
	ARfD	0.5 mg/kg bw	NOAEL = 50 mg/kg bw/d	AF= 100	Rat Developmental study	Mortality, clinical signs and decrease in bw gain
	AAOEL	N/A	N/A	N/A	N/A	N/A
	The agreed toxicological reference values for cymoxanil are as follows:					
	<u>Cymoxanil (10% in product) (EFSA Scientific Report (2008) 167, 1-116)</u>					

Classification	Repro. 2; H361fd, Acute Tox.4; H302, STOT RE 2; H373 (blood, thymus), Skin Sens. 1; H317; EU CLH and GB MCL (mandatory classification)				
AOEL	0.01 mg/kg bw/d	NOAEL = 1.3 mg/kg bw/d	AF= 100 +*75%	Dog 1-year study	Testes (organ weight, macroscopic and microscopic changes), epididymides (macroscopic and microscopic changes), liver (organ weight, histology), kidney (organ weight) and thymus (histology)
ADI	0.013 mg/kg bw/d	NOAEL = 1.3 mg/kg bw/d	AF= 100	Dog 1-year study	
ARfD	0.08 mg/kg bw	NOAEL = 8 mg/kg bw/d	AF= 100	Rabbit Teratogenicity study	Increased incidences of skeletal malformations, hydrocephaly and cleft palates; increased incidences of visceral malformations
AAOEL	N/A	N/A	N/A	N/A	N/A

The agreed toxicological reference values for fludioxonil are as follows:

Fludioxonil (5% in product) (EFSA Scientific Report (2007) 110, 1-85, Conclusion on the peer review of fludioxonil)

Classification	Not classified; EU CLH and GB MCL (mandatory classification)				
AOEL	0.59 mg/kg bw/d	NOAEL = 58.5 mg/kg bw/d	AF= 100	Dog RDT studies (90-day)	Liver; increased weight, hepatocyte hypertrophy, bile duct proliferation
ADI	0.37 mg/kg bw/d	NOAEL = 37 mg/kg bw/d	AF= 100	Rat 2-years	Liver; increased weight, hepatocyte hypertrophy, bile duct proliferation Kidney; increased weight, nephropathy
ARfD	N/A	N/A	N/A	N/A	N/A
AAOEL	N/A	N/A	N/A	N/A	N/A

¹ The retained CLP Regulation (EU) No. 1272/2008 as amended for Great Britain.

Dermal Absorption

Under the Article 7 evaluation of metalaxyl-M, the product Wakil XL (A9873C) has been evaluated as a representative use. As such, only the dermal absorption of metalaxyl-M has been evaluated.

The applicant proposed to meet the data requirements for dermal absorption, with the

submission of an *in vitro* dermal absorption study (■■■■■, 2015).

The finalised dermal absorption values to be applied to A9873C are summarised below:

	Metalaxyl-M	
	Value (%)	Reference
Concentrate	0.85	■■■■■ and ■■■■■, 2016
In-use dilutions	N/A	Seed treatment only

Groundwater metabolites – relevance assessment

Three metabolites of metalaxyl-M are predicted to occur in groundwater at concentrations above 0.1 µg/L: SYN546520, NOA409045 and CGA67868.

Metabolite CGA67868 is predicted to occur between 0.1 and 0.75 µg/L. The two other metabolites are predicted to occur in groundwater at levels above 0.75 µg/L.

Toxicological data relating to these groundwater metabolites have previously been evaluated at the EU level and have not been considered further under this application. A critical area of concern was raised concerning the genotoxic potential of NOA409045, based on a positive *in vitro* chromosome aberration assay. The applicant provided two *in vivo* micronucleus assays as an appropriate follow up to address the outstanding concerns regarding the clastogenic potential of NOA409045 (SANTE/11112/2019 Rev 5, 2020). The studies were conducted on NOA409045 and the racemic mixture CGA62826 (50% NOA409045 and 50% NOA436575) (■■■■■ 2015b and 2014, respectively). HSE concluded the study on the racemic mixture was not required to determine the clastogenic potential of NOA409045. HSE evaluated the study on the metabolite (see Appendix 2 of dRR B6 for details), the result of the study was negative. Therefore, the clastogenic potential of NOA409045 can be dismissed.

Assessment of the relevance of these metabolites according to the stepwise procedure of the guidance document SANCO 221/2000 Rev 11; 21/10/2021 is reported in dRR Part B 10. No metabolites were found to be relevant.

Combined toxicity assessment

Under the Article 7 evaluation of metalaxyl-M, the product Wakil XL (A9873C) has been evaluated as a representative use. As such, only the toxicity of metalaxyl-M has been considered, therefore combined toxicity between active substances present in Wakil XL (A9873C) has not been evaluated under the Article 7 evaluation.

3.5.1 Acute toxicity

A summary of the toxicological evaluation for A9873C 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 401)	> 2000 mg/kg bw (not classified)	1672.36 mg/kg Category 4 (SDS Wakil XL >2000 mg/kg, not classi-	Yes	None

		fied)		
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	>2000 mg/kg Not classified (SDS Wakil XL >2000 mg/kg, not classified)	Yes	None
LC ₅₀ inhalation, rat	Not submitted, not necessary. Justification presented in Error! Reference source not found. , Part B6	1.43 mg/L Category 4 (SDS Wakil XL, >2.29 mg/L MAC, not classified)	Yes	None
Skin irritation, rabbit (OECD 404)	Non- irritating (not classified)	Not irritant Not classified (SDS Wakil XL Not irritant, not classified)	Yes	None
Eye irritation, rabbit (OECD 405)	No irreversible damage.	Eye irritant Category 1 (SDS Wakil XL, Not irritant, not classified)	Yes	None
Skin sensitisation, guinea pig (OECD 406, M&K)	Non-sensitising	Skin sensitizer Category 1 (SDS Wakil XL, not classified)	Yes	None
Supplementary studies for combinations of plant protection products	No data – not required			

¹ Proposed acute toxicity classifications are based on A9873C study results.

Cymoxanil

The cymoxanil metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

Fludioxonil

There are no relevant metabolites for fludioxonil.

Metalaxyl-M

Data and toxicological studies on metabolites NOA409045, CGA67868 and SYN546520 with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment are submitted.

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

3.5.2 Operator exposure

A9873C is to be applied to large seeds (peas/beans) and various small seeds.

Industrial seed treatment - Large seeds

For large seeds there is only one proposed application rate, 2 kg product/tonne seed. Furthermore, the amount of seed treated per day is expected to be 75 tonnes for all seeds. Therefore, application to peas

(Use No. 1) represents the critical GAP for large seeds.

Operator exposure for use of A9638A was modelled using the “Seed-Treatment Operator EXposure” data (**Seed-TROPEX Model**) for industrial seed treatment in risk assessment for plant protection product [REDACTED], [REDACTED], [REDACTED], Worker Exposure During Seed Treatment and Sowing of Treated Seed in the UK and France: An Overview. Zeneca Agrochemicals, Fernhurst, Haslemere. Report No. TMF 4896.].

Multi-activity exposure was calculated as the cumulative exposure from the calibration, mixing/loading (fast-couple), bagging and cleaning tasks.

According to the exposure calculations, it can be concluded that the risk for the operator using A9638A on peas (critical use: Seed treatment of peas, max. 2 kg product/tonne seed) is acceptable with the use of gloves during mixing/loading, calibration and cleaning, except bagging, so this level of PPE has been assumed as standard. As the predicted exposure to cymoxanil for this clothing scenario exceeds the AOEL, operator exposure was estimated with the addition of respiratory protective equipment (RPE) during the cleaning task.

The outcome of the estimations are presented in the Part B Section 6.

Industrial seed treatment - Small seeds

For small seeds there is also only one proposed application rate, 2 kg product/tonne seed. Small seeds are treated at a throughput of 5,000 units/day, which is 0.5 tonne seed if the TGW is 1 g and 1 unit contains 100,000 seeds. Therefore, application to alfalfa (Use No. 21) represents the critical GAP for small seeds.

Estimation of operator exposure during the treatment of small seeds with A9873C was modelled using the **2004 Seed-TROPEX** study (sugar beet) [REDACTED] (2006). Determination of operator exposure to imidacloprid during treatment of sugar beet seeds with IMPRIMO® in France. Amended Final Report 04B033 HI, Rhodia Recherches et Technologies, Laboratoire d’Hygiène Industrielle, F-69162 Saint-Fons Cedex, France. SeedTROPEX Group].

Calculations according to the Seed-TROPEX study data predict an acceptable level of exposure to active substances for operators treating small seeds with A9873C, when a long sleeved work jacket and long trousers are worn with the addition of a non-woven coverall and chemical resistant gloves during the handling of product and cleaning equipment. For the hypothetical operator performing the multiple activities of mixing/loading and supervision/maintenance/cleaning of equipment, exposure was estimated to be less than 1% of the AOEL using the 75th percentiles of the data for body weights of 60 kg and 70 kg.

Mobile treaters and On-farm treatment: large and small seeds

The Seed-TROPEX model does not contain data for the assessment of exposure of operators treating seeds on mobile and on-farm treatment equipment.

However, exposure to operators treating seed on mobile or on-farm treatment equipment is considered to be in the same range or less than the exposure to operators working in static plants for the following reasons: treatment on mobile or on-farm is usually done outside, treatment capacities are estimated to be lower (0.5 to 2 tonnes/hour) on mobile or on-farm treatment equipment compared to static industrial equipment (2 to 9 tonnes/hour) and exposure time is likely to be shorter than in static plants.

Measurement of operator exposure

Although operator exposure is estimated to be below the AOEL of metalaxyl-M fludioxonil and cymoxanil during seed treatment, for cymoxanil this is only if RPE is worn during the cleaning of equip-

ment. A higher tier risk assessment has been performed to confirm levels of exposure for operator treating peas seeds with A9873C will be within acceptable levels without the requirement of RPE. This higher tier assessment is based on a study which measures operator exposure to prochloraz and fluquinconazole during the bagging and cleaning tasks. A detailed evaluation of that study is presented in Part B Section 6 Point 6.6.2.2.

Operator exposure using higher tier study data showed that during the treatment of peas seed, operator exposure to metalaxyl-M, fludioxonil, and cymoxanil is estimated to be below the AOEL using the Seed-TROPEX model to predict exposure from the mixing/loading and calibration tasks and data from the prochloraz study to estimate exposure from bagging and cleaning. Therefore, the outcome of the estimated operator exposure during seed treatment using higher tier study data assumes gloves are worn for the calibration, mixing/loading and cleaning tasks.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

HSE Chemicals Regulation Division (CRD), UK

Estimates using the Seed-TROPEX model predict that the proposed uses of 'Wakil XL' as a diluted seed treatment on vining and combining pea seeds will result in a level of systemic exposure to metalaxyl-M equal to 0.0454 mg/kg bw/day (equivalent to 57% of the AOEL of metalaxyl-M). The predicted exposure is within acceptable limits.

Estimates using the Seed-TROPEX model predict that the proposed uses of 'Wakil XL' will result in a level of exposure to metalaxyl-M equal to 0.0019 mg/kg bw/day (equivalent to 2% of the AOEL of metalaxyl-M) for operators not directly involved in the seed treatment process (e.g. forklift truck drivers) using no PPE.

Based on these exposure estimates and considering the classification of 'Wakil XL' with regards to human health, the following operator protection phrases are required for the operators being directly involved in the seed treatment process:

- Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when handling the concentrate, contaminated surfaces or handling treated seed.
- Operators must wear suitable protective clothing (coveralls) when bagging treated seed.

3.5.3 Worker exposure

Worker exposure for A9873C was modelled using the **Seed-TROPEX model** during the loading and sowing of treated seeds [REDACTED], Worker Exposure During Seed Treatment and Sowing of Treated Seed in the UK and France: An Overview. Zeneca Agrochemicals, Fernhurst, Haslemere. Report No. TMF 4896].

Outcome of the estimation and detailed calculations are presented in the Part B Section 6.

At this time, no acute AOEL has been set for any of the active substances. Consequently, no acute risk assessment has been provided.

Loading and sowing of treated seeds- large seeds

According to the exposure calculations, it can be concluded that the risk for the worker A9873C on peas (critical use: Loading and sowing treated large seeds, Work rate:10 hr/day) is acceptable with the use of gloves while loading hopper.

Loading and sowing of treated seeds- small seeds

As stated in the risk assessment for loading and sowing large seeds, dust is likely to be the main source of exposure during this activity. As the small seeds are treated by a different process to the large seeds, i.e. *via* coating/pelleting, levels of dust from handling/sowing vegetable seeds will be significantly lower than from handling/sowing large seeds. In addition, workers will handle a much greater volume of seed when sowing large seeds such as peas than when sowing the small seeds which are precision drilled. The risk assessment for workers sowing large seeds therefore provides a suitable risk envelope for small seed sowing operations.

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure is not required.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

HSE Chemicals Regulation Division (CRD), UK
--

Estimates using the Seed-TROPEX model predict a level of systemic exposure equivalent to 35% of the AOEL of metalaxyl-M for a worker loading/sowing treated seed without protection from clothing or PPE. This is within acceptable limits.

3.5.4 Bystander and resident exposure

In industrial seed treatment facilities the incidental presence of bystanders can be excluded by technical management measures. If occurring, exposure of bystanders would be of short duration and normally lower than that of seed treatment operators who are occupationally exposed all day long. The same applies for seed loading and sowing activities. Therefore, it is reasonable to assume that there will be no undue risk to persons being incidentally exposed to seed treatment or seed sowing operations.

Bystander and resident exposure is not applicable for seed treatment products and was therefore not performed.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

HSE Chemicals Regulation Division (CRD), UK
--

The treatment of vining and combing pea seeds is usually performed in professional plants where access is restricted to people working at the plant. Therefore, it is considered that bystanders and residents will not be exposed to 'Wakil XL' during the seed treatment process. Therefore, no resident/bystander exposure risk is expected. No further assessment is necessary.

Combined Exposure and Risk Assessment

The product is a mixture of three active substances.

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.'

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. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

The Hazard Index is < 1 . Thus, combined exposure to all active substances in A9873C is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments:
HSE notes that under the Article 7 evaluation of metalaxyl-M, the product 'Wakil XL' (A9873C) has been evaluated as a representative use. Therefore, only non-dietary exposure to the active substance metalaxyl-M has been evaluated. Thus, a combined exposure assessment for the proposed uses of 'Wakil XL' has not been considered.

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
<p>Name of authority: HSE Chemicals Regulation Division (CRD), UK</p> <p>‘Wakil XL’ was not the representative product for the approval of metalaxyl-M. ‘Wakil XL’ has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product ‘Wakil XL’ is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.</p> <p>‘A9873C’ (‘Wakil XL’) is a WG formulation containing 169.6 g/kg metalaxyl-M, 100 g/kg cymoxanil and 50 g/kg fludioxonil. The proposed uses in the GB are summarised in B0/B7 Table 7.1-1.</p> <p><u>Metalaxyl-M only:</u></p> <p>Acceptable plant and animal metabolism data, as well as feeding study data were submitted in the EU RAR for metalaxyl-M.</p> <p>Acceptable rotational crop metabolism data was submitted in the EU RAR for metalaxyl-M. No residues of metalaxyl-M above the LOQ of 0.01 mg/kg are expected in rotational crops.</p> <p>Sufficient processing data is available in the EU RAR for metalaxyl-M.</p> <p>Residues data from new residues trials; and trials data previously evaluated for a product assessment are relied on to support the proposed uses. Sufficient storage stability data is presented in the EU RAR to support the proposed uses.</p> <p>For details of the MRL considerations relating to the product, see the green box below.</p> <p>No chronic or acute consumer risk issues are expected as a result of the proposed uses based on the EU PRIMo and UK NEDI and NESTI calculations – ONLY APPLICABLE TO METALAXYL-M, consumer risk has not been assessed for cymoxanil or fludioxonil.</p> <p>Conclusion</p> <p>Authorisation for the proposed uses of ‘Wakil XL’ on peas at the proposed GAP can be recommended; with respect to metalaxyl-M.</p> <p>Data Requirements</p> <p>Extract stability data covering the analytical period in the submitted residue trials for metalaxyl-M in/on peas should be provided in order for the trials to be considered as ‘relevant trials’, rather than ‘supporting information’.</p>

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
<p>Name of authority: HSE Chemicals Regulation Division (CRD), UK</p> <p><u>Maximum residue levels (MRLs) - Metalaxyl-M only</u></p> <p>GB MRLs</p>

GB MRLs in force

The GB MRLs listed in Table 7.1-0a are relevant to the proposed uses of 'Wakil XL' in GB.

Active: metalaxyl-M **Error! Reference source not found.**

Plant residue definition for enforcement: Metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)

Animal residue definition for enforcement: Not required

Table 7.1-0a GB MRLs in force for metalaxyl-M relevant to the proposed uses in GB

Code	Commodity to which MRL applies	MRL required for proposed use (mg/kg)	GB MRL in force (as outlined in the GB MRL Statutory Register GB MRL decision no. 2022/013) (mg/kg)	Potential future GB MRL (mg/kg) [†]
0260030	Peas with pods	0.02*	0.02*	-

[†] *Agreed future MRLs outlined in the Register or proposed MRLs outlined in the [Published MRL reviews List](#)*

Conclusion on GB MRLs

On the basis of this evaluation, the existing GB MRLs are sufficient to accommodate the proposed uses in GB.

MRL supplementary information requirements (MRL confirmatory data) for GB MRLs

An MRL review relevant to GB has been conducted (EFSA, Article 12, 2015). This MRL review was a joint review of metalaxyl and metalaxyl-M.

No GB MRL data gaps relevant to the MRLs considered in this assessment were identified in the MRL review.

'Wakil XL' was not the representative product for the approval of metalaxyl-M. 'Wakil XL' has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Wakil XL' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.

3.6.1 Residues

Cymoxanil

A9873C is proposed for minor uses as a seed treatment on crops of fresh legumes (vining peas) and, pulses (combining peas).

Combining and vining peas are major crops in both northern and southern Europe, generally requiring 8 trials in each region.

The intended GAP for combining and vining peas is 1x20 g a.s./100kg seeds.

For combining peas, four trials are available for northern EU and four trials are available for southern EU at the cGAP for A9873C that demonstrate residues of cymoxanil in dry seeds will be < LOQ of

0.02 mg/kg at harvest. In one trial in northern EU peas sampled at PHI 136 days (dry stage) had a residue level of 0.02 mg/kg. This residue level was identified as an outlier using the Dixon test. No agronomic explanation for the unexpected high residue was found in the study but considering that the metabolism studies for cymoxanil indicate no residues in pulses are expected after seed treatment and that in the same trial peas and pods harvested at a shorter PHI (fresh pea stage) had residue levels below the LOQ, the value is considered an outlier. Therefore there are sufficient acceptable trials data available to support use on combining peas and to demonstrate that residues will be < LOQ.

For vining peas, sufficient acceptable trials data are available to support the cGAP for A9873C that demonstrate residues of cymoxanil will be < LOQ (0.02 mg/kg or 0.05 mg/kg) at harvest. Data are available for northern Europe only however, as the use is a seed treatment climatic zones are not considered to have a significant impact on residue levels and data from one zone are sufficient to support all zones.

The data submitted show that no exceedance of current EU MRLs for cymoxanil will occur.

Fludioxonil

A9873C is proposed for minor uses as a seed treatment on crops of fresh legumes (vining peas) and, pulses (combining peas).

Combining and vining peas are major crops in both northern and southern Europe, generally requiring 8 trials in each region.

The intended GAP for combining and vining peas is **1 x 10 g a.s./100 kg seed**.

For combining peas, four trials are available for northern EU and four trials are available for southern EU at the cGAP for A9873C that demonstrate residues of fludioxonil in dry seeds will be < LOQ of 0.02 mg/kg at harvest following seed treatment. In one trial in northern EU peas sampled at PHI 136 days (dry stage) had a residue level of 0.06 mg/kg. This residue level was identified as an outlier using the Dixon test. No agronomic explanation for the unexpected high residue was found in the study but considering that the metabolism studies for fludioxonil indicate no residues in pulses are expected after seed treatment and that in the same trial peas and pods harvested at a shorter PHI (fresh pea stage) had residue levels below the LOQ, the value is considered an outlier caused by cross-contamination. Therefore there are sufficient acceptable trials data are available to support use on combining peas and to demonstrate that residues will be < LOQ. These data can also be extrapolated to support the whole group of pulses (0300000) and the whole group of legume vegetables (0260000, including dwarf French beans, 0260010) in line with the current EU extrapolation guidelines, **SANCO 725/VI/95 Rev 10.3**.

For vining peas, nine acceptable trials data are available to support the cGAP for A9873C that demonstrate residues of fludioxonil will be < LOQ of 0.02 mg/kg at harvest. Data are available for northern Europe only; however as the use is a seed treatment the climatic zones are not considered to have a significant impact on residue levels. Residue trials were evaluated during the MRL review for fludioxonil (EF-SA, 2011) and residues in southern Europe from a foliar application resulting in residues below 0.02 mg/kg, so residues after a seed treatment use are not expected.

The data submitted show that no exceedance of current EU MRLs for fludioxonil will occur.

The intended uses of fludioxonil in the product A9873C are considered acceptable.

Metalaxyl-M

A9873C is proposed for minor uses as a seed treatment on crops of fresh legumes (vining peas) and, pulses (combining peas).

Combining and vining peas are major crops in both northern and southern Europe, generally requiring 8 trials in each region.

The intended GAP for combining and vining peas is 1x33.9 g a.s./100kg seeds.

For combining peas, seven trials are available for northern EU and five trials are available for southern EU at the cGAP for A9873C that demonstrate residues of metalaxyl-M in dry seeds will be <LOQ of 0.02 mg/kg at harvest. For dry beans, four trials are available for northern EU at the cGAP for A9873C that demonstrate residues of metalaxyl-M in dry seeds will be <LOQ of 0.02 mg/kg at harvest. As residues are < LOQ a reduced number of trials is acceptable to support the use and therefore there are sufficient acceptable trials data are available to support use on combining peas. These data can also be extrapolated to

support the whole group of pulses (0300000) and the whole group of legume vegetables (0260000) in line with the current EU extrapolation guidelines, **SANCO 7252/VI/95 Rev 10.3**.

For vining peas, twelve trials are available for northern EU and six trials are available for southern EU at the cGAP for A9873C that demonstrate residues of metalaxyl-M will be < LOQ of 0.02 mg/kg at harvest. For fresh beans, four trials are available for northern EU supporting the cGAP for A9873C that demonstrate residues of metalaxyl-M will be < LOQ of 0.02 mg/kg at harvest.

The data submitted show that no exceedance of current EU MRLs for metalaxyl-M will occur.

The intended uses of metalaxyl-M in the product A9873C are considered acceptable.

3.6.2 Consumer exposure

Cymoxanil

The output reports from the risk assessments are presented in Part B Section 7 **Error! Reference source not found..**

Table: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	22.0 % (based on GEMS/Food G06)
IEDI (% ADI) according to EFSA PRIMo	Not required as TMDI < 100%
IESTI RAC (% ARfD) according to EFSA PRIMo*	Beans (pulses): 1 % (based on UK infant
IESTI Processed (% ARfD) according to EFSA PRIMo*	Beans: 0.8 %

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed uses of cymoxanil in A9873C do not represent unacceptable acute and chronic risks for the consumer.

Fludioxonil

The output report from the chronic risk assessment is presented in Part B Section 7 **Error! Reference source not found..**

Table: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo3.1	60 % (based on NL Toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	Long-term consumer exposure is assessed using TMDI calculation.
IESTI (% ARfD) according to EFSA PRIMo3	Not applicable (no ARfD set for fludioxonil)

The proposed uses of fludioxonil in A9873C do not represent unacceptable chronic risks for the consumer. An acute assessment is not required.

Metalaxyl-M

The output reports from the chronic and acute risk assessments are presented in Part B Section **Error! Reference source not found..**

Table : Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	29 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Not required as TMDI < 100%
IESTI RAC (% ARfD) according to EFSA PRIMo 3.1*	Bovine, edible offals, other: 0.4 % (based on UK infant)
IESTI Processed (% ARfD) according to EFSA PRIMo 3.1*	Beans (with pods)/boiled: 0.1 %

* include raw and processed commodities if both values are required for PRIMo

The proposed uses of metalaxyl-M in A9873C do not represent unacceptable acute and chronic risks for the consumer.

Combined exposure and risk assessment

The product is a mixture of three active substances and for at least two of them an acute reference dose has been allocated. Therefore, combined acute and chronic exposures can be considered.

A request for Syngenta to provide combined risk assessments for the mixture product A9873C containing cymoxanil, fludioxonil and metalaxyl-M has been made by the UK Regulatory Authority.

A combined risk assessment has been provided irrespective of whether a dose addition approach is considered applicable and irrespective of whether or not the mode or mechanism of toxicity in mammals is the same for the three compounds in the mixture product.

Chronic consumer risk assessment from combined exposure

Analysis of the NEDIs provided from the UK risk assessment model demonstrates that the addition of the percentages of the respective ADIs for all active ingredients results in a value lower than 100%.

The highest _consumer_group sub group with the highest combined % of the ADI and the contributions from each of the active substances are summarised below. See Appendix 3 for detailed chronic risk assessments (NEDI) for each active substance.

The highest combined NEDI is for the UK TODDLER subgroup and represents 52% of the ADI.

Contribution from Fludioxonil is 36%

Contribution from Metalaxyl-M is 9%

Contribution from Cymoxanil is 7%

The addition of the %ADIs is a crude indicator of safety and is a considerable overestimate of risk for the following reasons:

- Some MRL values are used in the risk assessment (where STMR data are not available).
- It assumes that 100% of crops with established and proposed uses will contain residues at the STMR
- No account is taken of the potential reduction in residues during transport and storage or during commercial and domestic processing.
- The addition of the %ADIs from the UK NEDI calculations is an overestimate as the mixture product is not intended for use on all crops presented in the risk assessment and therefore the likelihood of joint exposure is much lower for crops not on the product label.
- It assumes that dose addition is applicable whereas in practice:
 - Different active substances may have ADIs based on different critical effects
 - Different active substances may have different routes of detoxification
 - Individuals may not be equally more-senesative than laboratory animals to the molecular

interactions related to multiple active substances.

- It assumes that any toxicity shared by the multiple active ingredients at high doses is relevant to potential interactions between NOELs.

In practice, the actual intake is likely to be considerably lower than the calculated values based up-on addition of the %ADIs for cymoxanil, fludioxonil and metalaxyl-M.

Acute consumer risk assessment from combined exposure

Analysis of the NESTIs provided from the UK risk assessment model demonstrates that the addition of the percentages contribution to the respective ARfDs for all active ingredients for each crop (considering all supported product uses) always results in a value lower than 100%. This is summarised below for the top 5 contributing commodities. See Appendix 3 for detailed acute risk assessment (NESTI) for each active substance.

The highest overall combined NESTI is for the consumption of Milk by the UK infant and represents 1.8% of the ARfD.

Milk (1.8% - UK infant)

Contribution from Cymoxanil is 1.6%

Contribution from Metalaxyl-M is 0.2%

Peas without pods (0.5% - UK infant)

Contribution from Cymoxanil is 0.5%

Contribution from Metalaxyl-M is 0%

Beans (0.5% - UK infant)

Contribution from Cymoxanil is 0.5%

Contribution from Metalaxyl-M is 0.1%

Other types of offal (0.5% - UK infant)

Contribution from Cymoxanil is 0.1%

Contribution from Metalaxyl-M is 0.4%

Beans without pods (0.5% - UK 7-10 year old child)

Contribution from Cymoxanil is 0.5%

Contribution from Metalaxyl-M is 0%

Therefore, the uses of A9873C in the UK proposed in this submission do not present an unacceptable acute risk to the consumer.

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

Cymoxanil

Studies on the aerobic and anaerobic degradation rates of cymoxanil and its metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 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 cymoxanil (**Cymoxanil, EFSA Journal 2008; 167, 1-116**). Additional information on the degradation of metabolite KQ960 in soil is detailed in Part B Section 8, Appendix 2 and should be considered at national re-registration.

Studies on the field dissipation rates of cymoxanil and its metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 are considered to be data provided in support of the active substance. However, since aerobic degradation in the laboratory resulted in half-lives far below the trigger of 60 days (**Cymoxanil, EFSA Journal 2008; 167:1-116**) studies were not submitted and not required for cymoxanil.

Studies on the mobility of cymoxanil and its metabolites IN-U3204, IN-W3595, IN-R3273, IN-T4226, IN-KP533, IN-KQ960 and IN-JX915 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 cymoxanil (**Cymoxanil, EFSA Journal 2008; 167, 1-116**). For Predicted Environmental Concentration in ground water only, according to the latest guideline (EFSA Journal 2013; 11(2):3114), the use of the geometric mean instead of the arithmetic mean for the K_{OC} is recommended. For cymoxanil and its respective metabolites, the individual values from which the geometric mean is calculated, are those established in the EU review (**Cymoxanil, EFSA Journal 2008; 167, 1-116**). Additional information on the sorption behavior of metabolite KQ960 is detailed in Part B Section 8, Appendix 2.

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 cymoxanil (**Cymoxanil, EFSA Journal 2008; 167, 1-116**).

Fludioxonil

Studies on the aerobic and anaerobic degradation rates of fludioxonil and its metabolite CGA192155 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 fludioxonil (**Fludioxonil; EFSA Scientific Report (2007) 110, 1-85**). There are no soil metabolites to be considered for seed treatment uses.

Studies on the field dissipation rates of fludioxonil and its metabolite CGA192155 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 fludioxonil (**Fludioxonil; EFSA Scientific Report (2007) 110, 1-85**). An additional field dissipation study has been carried out on fludioxonil to allow a modelled DT_{50} to be derived for seed treatment seed. Additional information on the field dissipation of fludioxonil is detailed in Part B Section 8, Appendix 2.

Studies on the mobility of fludioxonil 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 fludioxonil (**Fludioxonil; EFSA Scientific Report (2007) 110, 1-85**). For Predicted Environmental Concentration in ground water only, according to the latest guideline (EFSA Journal 2013; 11(2):3114), the use of the geometric mean instead of the arithmetic mean for the K_{OC} is recommended. For fludioxonil and its respective metabolite, the individual values from which the geometric mean is calculated, are those established in the EU review (**Fludioxonil; EFSA Scientific Report (2007) 110, 1-85**).

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 fludioxonil (**Fludioxonil; EFSA Scientific Report (2007) 110, 1-85**).

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 (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

Studies on the field dissipation rate of metalaxyl-M 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 (**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. For Predicted Environmental Concentration in ground water only, according to the latest guideline (EFSA Journal 2013; 11(2):3114), the use of the geometric mean instead of the arithmetic mean for the K_{OC} is recommended. For metalaxyl-M and its respective metabolites, the individual values from which the geometric mean is calculated, are those established in the EU review (**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 (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

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

Cymoxanil

Predicted Environmental Concentrations of cymoxanil and its metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 in soil (PEC_s) listed below are detailed in Part B Section 8 of this submission.

PECs for cymoxanil

The PEC_s of cymoxanil has been assessed in accordance with FOCUS guidelines, FOCUS groundwater crop interception values and the worst case DT_{50} value established in the EU review (**Cymoxanil, EFSA Journal 2008; 167, 1-116**) using CRD PEC_{SOIL} Excel spreadsheet. Based on the recommended use rate of 45 g a.s./ha on peas, the maximum initial Predicted Environmental Concentrations in soil ($PEC_{s,ini}$) of cymoxanil was 0.060 mg/kg. The field DT_{90} of cymoxanil is <365 d, and thus calculations estimating the potential accumulation of cymoxanil in soil were not performed.

PECs for IN-U3204

The PEC_s of IN-U3204 has been assessed in accordance with FOCUS guidelines, FOCUS groundwater crop interception values and the worst case DT_{50} values established in the EU review (**Cymoxanil, EFSA Journal 2008; 167, 1-116**) using CRD PEC_{SOIL} Excel spreadsheet. For IN-U3204, the proposed use pattern will lead to maximum $PEC_{s,ini}$ of 0.015 mg/kg. The field DT_{90} of IN-U3204 is <365 d, and thus calculations estimating the potential accumulation of IN-U3204 in soil were not performed.

PECs for IN-W3595

The PEC_s of IN-W3595 has been assessed in accordance with FOCUS guidelines, FOCUS groundwater crop interception values and the worst case DT_{50} values established in the EU review (**Cymoxanil, EFSA**

Journal 2008; 167, 1-116) using CRD PEC_{SOIL} Excel spreadsheet. For IN-W3595, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.004 mg/kg. The field DT₉₀ of IN-W3595 is <365 d, and thus calculations estimating the potential accumulation of IN-W3595 in soil were not performed.

PECs for IN-JX915

The PEC_S of IN-JX915 has been assessed in accordance with FOCUS guidelines, FOCUS groundwater crop interception values and the worst case DT₅₀ values established in the EU review (**Cymoxanil, EFSA Journal 2008; 167, 1-116**) using CRD PEC_{SOIL} Excel spreadsheet. For IN-JX915, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.007 mg/kg. The field DT₉₀ of IN-JX915 is <365 d, and thus calculations estimating the potential accumulation of IN-JX915 in soil were not performed.

PECs for IN-KQ960

The PEC_S of IN-KQ960 has been assessed in accordance with FOCUS guidelines, FOCUS groundwater crop interception values and the worst case DT₅₀ values established in the EU review (**Cymoxanil, EFSA Journal 2008; 167, 1-116**) using CRD PEC_{SOIL} Excel spreadsheet. For IN-KQ960, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.004 mg/kg. The field DT₉₀ of IN-KQ960 is <365 d, and thus calculations estimating the potential accumulation of IN-KQ960 in soil were not performed.

Fludioxonil

Predicted Environmental Concentrations of fludioxonil in soil (PEC_S) listed below are detailed in Part B Section 8 of this submission. The metabolic pathway for fludioxonil degradation in soil was determined from laboratory data. Fludioxonil is rapidly degraded in laboratory photolysis studies to form several degradation products, whilst degradation under the conditions of laboratory soil metabolism studies conducted in the absence of light was slower and no degradation products were isolated or identified. Therefore, for seed treatment use, these metabolites are not considered in PEC_S assessments.

PECs for fludioxonil

The PEC_S of fludioxonil has been assessed in accordance with FOCUS guidelines, FOCUS groundwater crop interception values and the worst case DT₅₀ value established in the EU review (**Fludioxonil; EFSA Scientific Report (2007) 110, 1-85**) (Tier I) and proposed in data point KCP 9.1.1.2 based on new data provided for this assessment (Tier II) using CRD PEC_{SOIL} Excel spreadsheet. Based on the recommended use rates of 22.5 g a.s./ha on peas, the maximum initial Predicted Environmental Concentrations in soil (PEC_{S,ini}) of fludioxonil were 0.030 mg/kg for Tier I and Tier II. In addition to the seasonal PEC_{S,ini} calculations, the potential accumulation (PEC_{S,accumulation}) of fludioxonil in soil following repeated applications of A9873C to peas 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 0.013 mg/kg (Tier I) and <0.001 mg/kg (Tier II) would be reached. The long term Predicted Environmental Concentration (PEC_{S,accumulation}) was calculated as 0.043 mg/kg (Tier I) and 0.031 mg/kg (Tier II).

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.

PECs for metalaxyl-M

The PEC_S of metalaxyl-M has been assessed in accordance with FOCUS guidelines, FOCUS groundwater crop interception values and the worst case DT₅₀ value established in the EU review (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**) using CRD PEC_{SOIL} Excel spreadsheet. Based on the recommended use rate of 76.3 g a.s./ha on peas, the maximum initial Predicted Environmental Concentrations in soil (PEC_{S,ini}) of metalaxyl-M was 0.102 mg/kg. The field DT₉₀ of metalaxyl-M is <365 d, and thus calculations estimating the potential accumulation of metalaxyl-M in soil were not performed.

PECs for NOA409045

The PEC_S of NOA409045 has been assessed in accordance with FOCUS guidelines, FOCUS groundwater

crop interception values and the worst case DT₅₀ values established in the EU review (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**) using CRD PEC_{SOIL} Excel spreadsheet. For NOA409045, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.070 mg/kg. The field DT₉₀ of NOA409045 is <365d, and thus calculations estimating the potential accumulation of NOA409045 in soil were not performed.

PECs for CGA67868

The PEC_S of CGA67868 has been assessed in accordance with FOCUS guidelines, FOCUS groundwater crop interception values and the worst case DT₅₀ values established in the EU review (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**) using CRD PEC_{SOIL} Excel spreadsheet. For CGA67868, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.004 mg/kg. The field DT₉₀ of CGA67868 is <365d, and thus calculations estimating the potential accumulation of CGA67868 in soil were not performed.

PECs for SYN546520

The PEC_S of SYN546520 has been assessed in accordance with FOCUS guidelines, FOCUS groundwater crop interception values and the worst case DT₅₀ values established in the EU review (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**) using CRD PEC_{SOIL} Excel spreadsheet. For SYN546520, the proposed use pattern will lead to maximum PEC_{S,ini} of 0.004 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 A9873C to peas 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 0.001 mg/kg would be reached.. The long term Predicted Environmental Concentration (PEC_{S,accumulation}) was calculated as 0.005 mg/kg.

PECs for A9873C

The PEC_S of A9873C has been assessed with the FOCUS groundwater crop interception values. Based on the maximum recommended use rate of 450 g A9873C/ha, the maximum initial Predicted Environmental Concentration in soil (PEC_{S,ini}) of A9873C will be 0.600 mg/kg.

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

Cymoxanil

Groundwater modelling on cymoxanil and its metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 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 cymoxanil and soil metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 in groundwater (PEC_{GW}) have been assessed with the standard FOCUS scenarios, the FOCUS PEARL v4.4.4 / FOCUS PELMO v5.5.3 / MACRO v5.5.4 models, using endpoints established in the EU review (**Cymoxanil, EFSA Journal 2008; 167, 1-116**), proposed in data points KCP 9.1.1 and 9.1.2 based on re-calculation of DT₅₀ and K_{FOC} values provided for this assessment and for the cymoxanil metabolite IN-KQ960 additional laboratory soil degradation study (■■■■, 2010) and adsorption study (■■■■, 2010a).

The maximum PEC_{GW} of cymoxanil at 1 m depth following 20 years use on peas and beans at a rate of 45 g a.s./ha from a growth state of BBCH 00 and 0% foliar interception, was less than 0.001 µg/L. The potential for the metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 to leach to groundwater has been assessed using the same approach.

The PEC_{GW} values of IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 were less than 0.1 µg/L in all scenarios.

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

Fludioxonil

Groundwater modelling on fludioxonil 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 metabolic pathway for fludioxonil degradation in soil was determined from laboratory data. Fludioxonil is rapidly degraded in laboratory photolysis studies to form several degradation products, whilst degradation under the conditions of laboratory soil metabolism studies conducted in the absence of light was slower and no degradation products were isolated or identified. Therefore, for seed treatment use, these metabolites are not considered in PEC_{GW} assessments.

The Predicted Environmental Concentration fludioxonil in groundwater (PEC_{GW}) has been assessed with the standard FOCUS scenarios, the FOCUS PEARL v4.4.4 / FOCUS PELMO v5.5.3 / MACRO v5.5.4 models, using endpoints established in the EU review (**Fludioxonil; EFSA Scientific Report (2007) 110, 1-85**) and proposed in data points KCP 9.1.1 and 9.1.2 based on re-calculations of DT₅₀ and K_{FOC} values provided for this assessment.

The PEC_{GW} of fludioxonil at 1 m depth following 20 years use on peas and beans at a rate of 22.5 g a.s./ha from a growth state of BBCH 00 and 0% foliar interception, was less than 0.001 µg/L in all scenarios.

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

Metalaxyl-M

Groundwater modelling on metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 has not been previously reviewed at 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 groundwater (PEC_{GW}) has been assessed with the standard FOCUS scenarios, the FOCUS PEARL v4.4.4 / FOCUS PELMO v5.5.3 / MACRO v5.5.4 models, using endpoints established in the EU review (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**) and proposed in data points KCP 9.1.1 and 9.1.2 based on re-calculations of DT₅₀ and K_{FOC} values provided for this assessment.

The maximum PEC_{GW} of metalaxyl-M at 1 m depth following 20 years use on peas and beans at a rate of 78.75 g a.s./ha (PEC_S for metalaxyl-M and its soil metabolites was conducted at an elevated rate of 78.75 g a.s./ha instead of the maximum application rate of 76.3 g a.s./ha as given in the critical GAP) from a growth state of BBCH 00 and 0% foliar interception was 0.001 µg/L. The potential for the metabolites NOA409045, CGA67868 and SYN546520 to leach to groundwater has been assessed using the same approach.

The maximum PEC_{GW} of the metabolite NOA409045 was 3.53 µg/L in Hamburg scenario.

The maximum PEC_{GW} of the metabolite SYN546520 was 13.4 µg/L / 2.89 µg/L (Tier 1 / 2) in Hamburg and Jokioinen scenario.

The maximum PEC_{GW} of the metabolite CGA67868 was 0.107 µg/L in Hamburg scenario.

An assessment concluding the non-relevance of NOA409045, SYN546520 and CGA67868 in groundwa-

ter is presented in the Part B Section 10 of this submission.

Based on the assessment, 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.

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

Cymoxanil

Surface water modelling on cymoxanil and its metabolites IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533 and M5 has not been previously reviewed at EU level and is provided in support of this assessment in Part B Section 8, Appendix 3.

The Predicted Environmental Concentration of cymoxanil and its metabolites in surface water and sediment (PEC_{sw} and PEC_{sed}) following entry via drainage have been assessed according to standard Tier I calculations recommended in the national requirements in the UK (CRD 2016)². Since the present use is a seed treatment, spray drift can be excluded as a potential entry path to surface water. For the Tier I drainage assessments, applications of cymoxanil were assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case.

The PEC_{sw} and PEC_{sed} have been assessed using endpoints established in the EU review (**Cymoxanil, EFSA Journal 2008; 167, 1-116**) and for the cymoxanil metabolite IN-KQ960 additional adsorption study (■■■■, 2010).

Based on the recommended use on peas at a rate of 45 g a.s./ha and application at BBCH 00, the PEC_{sw} and PEC_{sed} values have been calculated using the Tier I drainage assessment. The maximum PEC_{sw} and PEC_{sed} values for cymoxanil due to drainage were 6.58 µg/L and 1.18 µg/L respectively.

The EXCEL “MACRO Drainflow Tool” together with FOCUS MACRO (v4.3b) model was used for a Higher Tier drainage assessment of cymoxanil since the Tier I PEC_{sw} drainage calculation exceeded the regulatory acceptable concentration (RAC) of 4.4 µg/L according to national requirements in the UK². The maximum Higher Tier PEC_{sw} value for cymoxanil due to drainage was 2.12 µg/L under wet weather scenario.

The Predicted Environmental Concentration of the metabolites IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533 and M5 in surface water and sediment (PEC_{sw} and PEC_{sed}) due to drainage have been assessed using the same approach.

The maximum PEC_{sw} and PEC_{sed} values for IN-U3204 via drainage were 1.62 µg/L and 0.152 µg/L respectively.

The maximum PEC_{sw} and PEC_{sed} values for IN-W3595 via drainage were 1.11 µg/L and 0.451 µg/L respectively.

The maximum PEC_{sw} and PEC_{sed} values for IN-KQ960 via drainage were 0.933 µg/L and 1.82 µg/L respectively.

The maximum PEC_{sw} and PEC_{sed} values for IN-JX915 via drainage were 3.46 µg/L and 0.364 µg/L respectively.

The maximum PEC_{sw} and PEC_{sed} values for IN-T4226 via drainage were 0.523 µg/L and 0.218 µg/L respectively.

² <https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/fate/index.htm> (accessed 2020/04/27)

The maximum PEC_{SW} and PEC_{SED} values for IN-R3273 via drainage were 2.01 µg/L and 0.131 µg/L respectively.

The maximum PEC_{SW} and PEC_{SED} values for IN-KP533 via drainage were 1.09 µg/L and 1.59 µg/L respectively.

The maximum PEC_{SW} and PEC_{SED} values for M5 via drainage were 1.51 µg/L and <0.001 µg/L respectively.

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

Fludioxonil

Surface water modelling on fludioxonil and its metabolite CGA192155 has not been previously reviewed at EU level and is provided in support of this assessment in Part B Section 8, Appendix 3.

The Predicted Environmental Concentration of fludioxonil in surface water and sediment (PEC_{SW} and PEC_{SED}) following entry via drainage have been assessed according to standard Tier I calculations recommended in the national requirements in the UK (CRD 2016)². Since the present use is a seed treatment, spray drift can be excluded as a potential entry path to surface water. For the Tier I drainage assessments, applications of fludioxonil were assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case.

The PEC_{SW} and PEC_{SED} have been assessed using endpoints established in the EU review (**Fludioxonil; EFSA Scientific Report (2007) 110, 1-85**).

Based on the recommended use on peas at a rate of 22.5 g a.s./ha and application at BBCH 00, the PEC_{SW} and PEC_{SED} values have been calculated using the Tier I drainage assessment. The maximum PEC_{SW} and PEC_{SED} values for fludioxonil due to drainage were 0.014 µg/L and 0.053 µg/L respectively.

The Predicted Environmental Concentration of the metabolite CGA192155 in surface water and sediment (PEC_{SW} and PEC_{SED}) due to drainage have been assessed using the same approach. The maximum PEC_{SW} and PEC_{SED} values for CGA192155 were 0.001 µg/L and 0.003 µg/L respectively.

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

Metalaxyl-M

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

The Predicted Environmental Concentration of metalaxyl-M in surface water and sediment (PEC_{SW} and PEC_{SED}) following entry via drainage have been assessed according to standard Tier I calculations recommended in the national requirements in the UK (CRD 2016)². Since the present use is a seed treatment, spray drift can be excluded as a potential entry path to surface water. For the Tier I drainage assessments, applications of metalaxyl-M were assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case.

The PEC_{SW} and PEC_{SED} have been assessed using endpoints established in the EU review (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

Based on the recommended use on peas and beans at a rate of 76.3 g a.s./ha and application at BBCH 00, the PEC_{SW} and PEC_{SED} have been calculated using the Tier I drainage assessment. The maximum PEC_{SW} and PEC_{SED} values for metalaxyl-M were 11.2 µg/L and 10.5 µg/L respectively.

The Predicted Environmental Concentration of the metabolite NOA409045 in surface water and sediment (PEC_{SW} and PEC_{SED}) due to drainage have been assessed using the same approach. The maximum PEC_{SW} and PEC_{SED} values for NOA409045 were 7.63 µg/L and 11.24 µg/L respectively.

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

PEC_{SW} and PEC_{SED} for A9873C

Since spray drift is not a relevant entry path for seed treatments, the PEC_{SW} for the formulation was not assessed.

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})

Cymoxanil

The fate and behaviour in air of cymoxanil was evaluated during EU review (**Cymoxanil, EFSA Journal 2008; 167, 1-116**). No additional studies have been performed.

Cymoxanil is directly incorporated into the soil via treated seed since A9873C is exclusively used as seed dressing. Furthermore, the vapour pressure of cymoxanil is low (1.5×10^{-4} Pa at 20°C), and, classifies as slightly volatile. Consequently, significant losses due to volatilisation are not expected. Thus, PEC_{air} is deemed not required for the active substance cymoxanil.

Fludioxonil

The fate and behaviour in air of fludioxonil was evaluated during EU review (**Fludioxonil; EFSA Scientific Report (2007); 110:1-85**). No additional studies have been performed.

Fludioxonil is directly incorporated into the soil via treated seed since A9873C is exclusively used as seed dressing. Furthermore, the vapour pressure of fludioxonil is very low (3.9×10^{-7} Pa at 25°C), and, as expected, fludioxonil was found to be non-volatile from soil. Consequently, there will be no relevant atmospheric exposure or contamination of rainwater. Thus, PEC_{air} is deemed not required for the active substance fludioxonil.

Metalaxyl-M

The fate and behaviour in air of metalaxyl-M was evaluated during EU review (**Metalaxyl-M, 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 the active substance metalaxyl-M is regarded as volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance 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 DT_{50} (< 2 days), the exposure by volatilisation is considered negligible. Moreover, A9873C is a seed treatment and the seeds are buried into soil which reduces volatilisation. Thus, PEC_{air} is deemed not required for metalaxyl-M.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

Birds

The acute and long-term risks of A9873C to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with metalaxyl-M, fludioxonil and cymoxanil, and maximum residues occurring on food items (seeds, seedlings) following applications according to the proposed use pattern.

Risk of secondary poisoning has also been assessed, as fludioxonil has $\log P_{ow} > 3.0$. The risk to birds 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 of fludioxonil (including secondary poisoning), indicating that the risk to birds is acceptable following use of A9873C according to the proposed use pattern.

A potential risk has been identified for large granivorous and small omnivorous birds exposed to metalaxyl-M and cymoxanil residues following the consumption of A9873C treated seeds or shoots from treated seeds, respectively.

When consideration is given to more realistic exposure parameters i.e. relevant focal species, species-specific portion of diet (PD), FIR/bw and portion of diet obtained in treated areas (PT), the refined long-term risks of metalaxyl-M and cymoxanil to birds is considered to be acceptable.

Mammals

The acute and long-term risks of A9873C to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with A9873C, cymoxanil, fludioxonil and metalaxyl-M and maximum residues occurring on food items (seeds, seedlings) following applications according to the proposed use pattern.

Risk of secondary poisoning has also been assessed, as fludioxonil has $\log P_{ow} > 3.0$.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk of fludioxonil (including secondary poisoning), indicating that the risk to mammals is acceptable following use of A9873C according to the proposed use pattern.

A potential risk has been identified for small omnivorous mammals exposed to metalaxyl-M, cymoxanil and cymoxanil/fludioxonil/metalaxyl-M mixture residues in seeds and for small omnivorous mammals exposed to cymoxanil residues in seedlings.

When consideration is given to more realistic exposure parameters i.e. species-specific portion of diet (PD), FIR/bw, de-husking behaviour and portion of diet obtained in treated areas (PT), the refined acute and long-term risks of cymoxanil and metalaxyl-M and to the cymoxanil/fludioxonil/metalaxyl-M mixture to mammals consuming A9873C treated seeds and seedlings is considered to be acceptable.

Other terrestrial wildlife

Studies with terrestrial amphibian and reptile species are not data requirements under Regulation (EU) No 544/2011 and 545/2011. In addition, there is currently no guidance addressing terrestrial life stages of amphibians and reptiles in PPP risk assessments. Therefore, the risk assessment provided above for birds and mammals is considered to be protective of terrestrial amphibian and reptile species.

3.8.2 Effects on aquatic species

The PEC/RAC ratios and RQ_{mix} values, using worst-case PEC_{sw} values for cymoxanil, fludioxonil and metalaxyl-M and their metabolites are less than the trigger value of 1, except for long-term risk to fish for cymoxanil and the cymoxanil/fludioxonil/metalaxyl-M mixture. The PEC/RAC ratios using higher tier PEC_{sw} for cymoxanil are less than the trigger of 1, indicating that the risk to aquatic organisms is acceptable following use of A9873C according to the proposed use pattern.

3.8.3 Effects on bees

The risk of A9873C to adult honeybees was assessed from Toxicity Exposure Ratios (TERs) following (SANCO/10329/2002 rev.2 (final), October 17, 2002) and the EPPO 2010 scheme. The risk from contact exposure is considered acceptable for seed treatments. All the acute and chronic oral TERs for cymoxanil, fludioxonil and metalaxyl-M are less than the relevant triggers, indicating that the risk to honeybees is acceptable following use of A9873C, according to the proposed use pattern.

The EPPO scheme suggests that effects on growth or development can be excluded when considering cymoxanil, fludioxonil and metalaxyl-M are not an IGR. To further demonstrate the low risk, the chronic larval risk of A9873C to honeybees was assessed from ETRs following EPPO 2010 scheme. Risk was estimated from larval studies with cymoxanil (formulated as A16148C FS), fludioxonil (formulated as A8240M FS) and metalaxyl-M (formulated as A13947A), and exposure calculated from potential residues in pollen / nectar and the measure of consumption of larvae. The TER values are less than the relevant trigger, indicating that the risk to larval honeybees is acceptable following use of A9873C, according to the proposed use pattern.

3.8.4 Effects on other arthropod species other than bees

The Tier II, extended laboratory study with *Aleochara bilineata* and *Orius laevigatus* showed acceptable in-field effects from application of A9873C as a seed treatment. In addition, acceptable risk to the soil macro-organisms *Folsomia candida* and *Hypoaspis aculeifer* following the use of A9873C treated seed was demonstrated under Point 9.8 of this document. The risk to non-target arthropods is therefore acceptable following use of A9873C according to the proposed use pattern.

A risk assessment for off-field exposure is not relevant for seed treatments.

3.8.5 Effects on soil organisms

Earthworms

The acute and long-term risk of A9873C to earthworms is acceptable following use of A9873C according to the proposed use pattern.

Other soil macro-organisms

The risk of A9873C to other non-target soil macro-organisms, as represented by Collembola and *Hypoaspis aculeifer*, is acceptable following use of A9873C according to the proposed use pattern.

Soil micro-organisms

The risk of A9873C, cymoxanil, fludioxonil, metalaxyl-M and metabolites for micro-organisms was evaluated by comparison of the maximum concentrations with effects $\leq 25\%$ derived from laboratory tests, with maximum PEC_s.

All the effect levels exceeded the relevant PEC_s values, indicating that the risk to soil micro-organisms is acceptable following the use of A9873C according to the proposed use pattern.

3.8.6 Effects on non-target terrestrial plants

The formulation A9873C is a fungicide seed treatment and as such risk assessment for non-target terrestrial plants is not required.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not required.

3.9 Relevance of metabolites (Part B, Section 10)

Cymoxanil

The cymoxanil metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 are not predicted to occur in groundwater at concentrations above 0.1 µg/L (see A9873C 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 not required.

Fludioxonil

There are no relevant metabolites for fludioxonil.

Metalaxyl-M

The metalaxyl-M metabolites NOA409045, CGA67868 and SYN546520 are predicted to occur in groundwater at concentrations above 0.1 µg/L (see A9873C 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:

Summary of the relevance assessment for NOA409045

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC _{GW}	3.53 µg/L
			Based on	Modelling result using FOCUS PEARL v4.4.4 / Peas 1 x 78.75 g a.s./ha BBCH 00, 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)	<1%
			#ADI based on	0.5 mg/kg bw/day (28 day sub-chronic (oral), NOAEL = 1000 mg/kg bw/day)

- 100 fold inter & intraspecies safety factor & additional 10 fold safety factor for extrapolation to chronic exposure & additional 2 fold safety factor for NOA409045 content in the test material

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:

Summary of the relevance assessment for SYN546520

Summary of the Relevance Assessment for B-TNE 10210				
	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC _{GW}	13.4 µg/L, Tier 1 2.89 µg/L, Tier 2
			Based on	Modelling result using FOCUS PEARL v4.4.4 / Peas 1 x 78.75 g a.s./ha BBCH 00, Hamburg / Jokioinen sceanrios. (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 (>0.75µg/L)
	STEP 5		Refined risk assessment	Acceptable

	Predicted exposure (% of ADI)	<2,5%
	#ADI based on	0.1 mg/kg bw/day (28 day sub-chronic (oral), NOAEL = 1000 mg/kg bw/day

- 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:

Summary of the relevance assessment for CGA67868

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC _{GW}	0.107 µg/L
			Based on	Modelling result using FOCUS PEARL v4.4.4 / Peas 1 x 78.75 g a.s./ha BBCH 00, 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

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

WAKIL XL contains fludioxonil which is approved as a candidate for substitution because it meets two of PBT criteria.

The conclusion of the comparative assessment will be provided separately.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	This assessment concerns evaluation of metalaxyl-M only.

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	None

Appendix 1 Copy of the product authorization

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	N/A

Appendix 2 Copy of the product label

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	N/A

Appendix 3 Letter of Access

Relevant letters of access provided separately.

Appendix 4 Lists of data considered for national authorisation

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	██████	02/12/2011	A9873C - Chemical characterization of batch KWL0K111 Report No. 123798 Document No. VV-400774 , A9873C_10212 Test Facility Syngenta Crop Protection GLP Unpublished	N	N	Expired	SYN	Y KIIIA 2
KCP 2.1	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIIIA 2.1
KCP 2.2	██████	19/01/2012	A9873C - Safety Study Report No. HT11/603 Document No. VV-400776 , A9873C_10215 Test Facility Syngenta Technology & Projects GLP Unpublished	N	N	Expired	SYN	Y KIIIA 2.2
KCP 2.3	██████	19/01/2012	A9873C - Safety Study Report No. HT11/603 Document No. VV-400776 , A9873C_10215 Test Facility Syngenta Technology & Projects GLP Unpublished	N	N	Expired	SYN	Y KIIIA 2.2
KCP 2.4	██████	12/01/2012	A9873C - Physical properties of batch KWL0K111 Report No. 123831	N	N	Expired	SYN	Y

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?
			Document No. VV-400775 , A9873C_10214 Test Facility Syngenta Crop Protection GLP Unpublished					KIIIA 2.2
KCP 2.6		12/01/2012	A9873C - Physical properties of batch KWL0K111 Report No. 123831 Document No. VV-400775 , A9873C_10214 Test Facility Syngenta Crop Protection GLP Unpublished	N	N	Expired	SYN	Y KIIIA 2.2
KCP 2.7		03/10/2013	Ref1 A9873C - StoSta and shelf life (2we 54°C) - HDPE Report No. Document No. VV-406461 , A9873C_10311 A9873C_10217 Test Facility Ciba-Geigy Not GLP Unpublished	N	N	-	SYN	Y KIIIA 2.7
KCP 2.7		12/06/2014	A9873C - Storage stability and shelf life statement (2 years 20 °C) in packaging made of HDPE Report No. 300021780 Document No. VV-407964 , A9873C_10337 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIIIA 2.7
KCP 2.7		24/06/1999	Report on product stability (18 weeks 30°C, bag made of polyethylene) Report No. 14546945 Document No. VV-117175 , CGA173506/4997 Test Facility Novartis Crop Protection Münchwilen AG Not GLP Unpublished	N	N	Expired	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 2.7		26/01/1999	Report on product stability (18 weeks 30°C, polypropylene container) Report No. 14547068 Document No. VV-111577 , CGA173506/1310 Test Facility Novartis Crop Protection Münchwilen AG GLP Unpublished	N	N	Expired	SYN	-
KCP 2.7		19/09/2000	Report on product stability (2 years 20°C, bag made of polyethylene) Report No. 34686321 Document No. VV-285268 , CGA173506/5251 Test Facility Novartis Crop Protection Münchwilen AG Not GLP Unpublished	N			SYN	
KCP 2.7		19/09/2000	Report on product stability (2 years 20°C, polypropylene container) Report No. 34689467 Document No. VV-285269 , CGA173506/5254 Test Facility Novartis Crop Protection Münchwilen AG Not GLP Unpublished	N	N	Expired	SYN	-
KCP 2.8.1		06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIII A 2.1
KCP 2.8.2		06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219	N	N	-	SYN	Y KIII A 2.1

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?
			Test Facility Syngenta Crop Protection Not GLP Unpublished					
KCP 2.8.3		06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIIIA 2.1
KCP 2.8.5.1		12/01/2012	A9873C - Physical properties of batch KWL0K111 Report No. 123831 Document No. VV-400775 , A9873C_10214 Test Facility Syngenta Crop Protection GLP Unpublished	N	N	Expired	SYN	Y KIIIA 2.4
KCP 2.8.5.1		06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIIIA 2.1
KCP 2.8.5.2		12/01/2012	A9873C - Physical properties of batch KWL0K111 Report No. 123831 Document No. VV-400775 , A9873C_10214 Test Facility Syngenta Crop Protection GLP Unpublished	N	N	Expired	SYN	Y KIIIA 2.4
KCP 2.8.5.3		06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIIIA 2.1

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 2.8.7	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIIIA 2.1
KCP 2.10	██████	09/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. SMN10736 Document No. VV-400777 , A9873C_10218 Test Facility Syngenta Biosciences Pvt. Ltd. Not GLP Unpublished	N	N	-	SYN	Y KIIIA 2.10
KCP 2.10	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIIIA 2.1
KCP 5.1.1	██████ ██████	17/12/2002	Analytical method AFA-1318/2 - Content of CGA329351 and CGA351920 in A9873C and A9873D by chiral LC Report No. AFA-1318/2 Document No. VV-123832 , CGA173506/5568 A9873C_10314 Test Facility Syngenta Crop Protection Münchwilen AG Not GLP Unpublished	N	N	-	SYN	Y KIIIA 5.1
KCP 5.1.1	██████	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	N	N	-	SYN	Y KIIIA 5.1

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?
			Unpublished					
KCP 5.1.1		15/12/2014	Statement on Validation of the Analytical Method SD-1751/1 for the determination of CGA72649 and CGA363736 in A9873C metalaxyl-M/cymoxanil/fludioxonil WG Report No. 300031476 Document No. VV-28929 , A9873C_10344 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-		Y KIIIA 5.1
KCP 5.1.1		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	N	Expired	SYN	Y KIIIA 5.1
KCP 5.1.1		05/10/1998	Analytical method CGA 329351, CGA 173506 and cymoxanil in formulation (WG) by liquid chromatography Report No. AF-1318/2 Document No. VV-124572 , A9873C_10312 CGA173506/1254 Test Facility Novartis Crop Protection Mönchwil AG GLP Unpublished	N	N	Expired	SYN	Y KIIIA 5.1
KCP 5.1.1		24/06/1999	Report on validation of analytical method AF-1318/2 Report No. 59202 Document No. VV-292097 , CGA173506/4974 A9873C_10313 Test Facility Novartis Crop Protection Mönchwil AG GLP	N	N	Expired	SYN	Y KIIIA 5.1

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?
			Unpublished					
KCP 5.1.1		09/01/2003	Report on validation of analytical method - AFA-1318/2 Report No. 109644 Document No. VV-293344 , CGA173506/5571 A9873C_10315 Test Facility Syngenta Crop Protection AG Not GLP Unpublished	N	N	-	SYN	Y KIIIA 5.1
KCP 5.1.2.5		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Met-alaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2010/98 Document No. VV-312513 , CGA173506/4962 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCP 5.1.2.5		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Met-alaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2011/98 Document No. VV-312406 , CGA173506/4963 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCP 5.1.2.5		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Met-alaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV-312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3

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 5.1.2.5		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2013/98 Document No. VV-312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCP 5.1.2.5		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2014/98 Document No. VV-312409 , CGA173506/4966 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCP 5.1.2.5		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV-312410 , CGA173506/4967 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCP 5.1.2.5		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV-330998 , CGA173506/5506 Test Facility ADME - Bioanalyses GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCP		30/06/2003	Determination of Residues of Metalaxyl-M, Fludioxo-	N	N	Expired	SYN	Y

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?
5.1.2.5			nil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV-328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished					KIIA 6.3
KCP 5.1.2.5		01/08/2003	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV-340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCP 5.2.1		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	New study never submitted before to this country	SYN	N
KCP 5.2.1		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	New study never submitted before to this country	SYN	N
KCP 5.2.1		2013	Independent Laboratory Validation of Multi-Residue Method DFG S19 for the Determination of Residues of Cymoxanil in Tomato, Grapes, Oilseed Rape and	N	Y	Syngenta reached agreement with the data owner to access the study. Data owner to	(SYN access)	Y KIIIA 5.2

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?
			Wheat Grain using LC-MS/MS - DuPont-35770. Výzkumný ústav organických syntéz a.s. (Research Institute for Organic Syntheses, Inc.) GLP Unpublished			provide further details directly if required		
KCP 5.2.5		2013	Independent Laboratory Validation for the Determination of Residues of Cymoxanil and IN-KQ960 in Water (Drinking and Stream) Using LC-MS/MS. Report DuPont -35792 GLP Unpublished	N	Y	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	(SYN access)	Y KIIIA 5.2
KCP 5.2.1		15/10/2014	Fludioxonil – Validation of the QuEChERS Method for the Determination of Fludioxonil Residues in Crop Matrices by LC-MS/MS Report No. P 3446 G Document No. VV-410631 , CGA173506_11710 Test Facility PTRL Europe GLP Unpublished	N	N	Expired	SYN	Y KIIIA 5.2
KCP 5.2.1		05/12/2014	Fludioxonil – Independent Laboratory Validation of the QuEChERS Method for the Determination of Fludioxonil Residues in Crop Matrices by LC-MS/MS Report No. 20140189 Document No. VV-410968 , CGA173506_11723 Test Facility Innovative Environmental Services GLP Unpublished	N	N	Expired	SYN	Y KIIIA 5.2
KCP 5.2.1		2013	Validation of Multi-Residue Method DFG S19 (LC-MS/MS module) for the Determination of Residues of Cymoxanil in Tomato, Grapes, Oilseed Rape and Wheat Grain. DuPont-35769. DuPont Report No. 35769	N	N	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	SYN	Y KIIIA 5.2

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?
			Eurofins Agroscience Services Chem GmbH (EAS Chem) GLP Unpublished					
KCP 5.2.1		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	N	Expired	SYN	Y KIIIA 5.2
KCP 5.2.2		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 Envigo CRS Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.2.2		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 Eurofins Agroscience Services EcoChem 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 5.2.2	██████	02/04/2009	Fludioxonil - Magnitude of residues in animal tissues following repeated oral administration to the laying hen Report No. T001339-08 1983/108-D2149 Document No. VV-383645 , CGA173506_11440 Test Facility Covance Laboratories Ltd. GLP Unpublished	Y	N	Expired	SYN	Y KIIIA 5.2
KCP 5.2.2	██████	24/02/2009	Validation of residue method GRM025.03A for total fludioxonil (CGA173506) and metabolites as CGA192155 in animal matrices (milk, eggs, muscle, fat, liver, kidney and whole blood) Report No. T001341-08-REG Document No. VV-382790 , CGA173506_11403 Test Facility ADME - Bioanalyses GLP Unpublished	N	N	Expired	SYN	Y KIIIA 5.2
KCP 5.2.2	██████	24/09/2008	Amended - Validation of Residue Method GRM025.03A for Total Fludioxonil (CGA173506) and Metabolites as CGA192155 in Animal Matrices (milk, eggs, muscle, fat, liver, kidney and whole blood) Report No. T001341-08-REG GRM025.03A SYN/FLU/08001 Document No. VV-505721 , CGA173506_50427 Test Facility Eurofins - ADME Bioanalyses GLP Unpublished	N	N	Expired	SYN	Y KIIIA 5.2
KCP 5.2.2	██████	26/02/2009	Fludioxonil - Analytical Method for the Determination of Residues of Total Fludioxonil (CGA173506) and Metabolites as CGA192155 in Animal Matrices (milk, eggs, muscle, fat, liver, kidney and whole blood). Final Determination by LC-MS/MS	N	N	Expired	SYN	Y KIIIA 5.2

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?
			Report No. GRM025.03A Document No. VV-127758 , CGA173506_11402 Test Facility ADME - Bioanalyses GCP Unpublished					
KCP 5.2.2		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 Eurofins Agrosience Services Chem GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIIA 5.2
KCP 5.2.5		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	-	SYN	N
KCP 5.2.5		04/04/2016	Fludioxonil – Independent Laboratory Validation (ILV) of Analytical Method GRM025.01A for the Determination of Residues of Fludioxonil (CGA173506) and its Metabolites CGA192155 and CGA339833 in Water Report No. CGA173506DW Document No. VV-462757 , CGA173506_11942 Test Facility CIP Chemisches Institut Pforzheim GmbH	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?
			GLP Unpublished					
KCP 5.2.5		2010	Analytical method for the determination of cymoxanil and IN-KQ960 in water (pond, stream, well, and tap) using LC/MS/MS Report DuPont-27500, Revision No. 1 GLP Unpublished	N	N	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	(SYN access)	Y KIIIA 5.2
KCP 5.2.5		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	New study never submitted before to this country	SYN	N
KCP 5.2.5		01/07/2015	Metalaxyl-M – Validation of Analytical Method for the Determination of Metalaxyl-M Metabolite CGA67868 in Water Report No. S14-05740 Document No. VV-412805 , CGA092370_10006 Test Facility Eurofins Agrosience Services Chem SAS GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 7.1.1		31/07/1998	Acute oral toxicity in the rat. Report No. 983060 Document No. VV-376066 , CGA173506/1166 Test Facility GLP Unpublished	Y	N	Expired	SYN	Y KIIIA 7.1.1

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 7.1.2		04/08/1998	Acute dermal toxicity in the rat. Report No. 983061 Document No. VV-376067 , CGA173506/1167 Test Facility GLP Unpublished	Y	N	Expired	SYN	Y KIIIA 7.1.1
KCP 7.1.4		04/08/1998	Acute dermal irritation/corrosion in the rabbit. Report No. 983062 Document No. VV-376068 , CGA173506/1168 Test Facility GLP Unpublished	Y	N	Expired	SYN	Y KIIIA 7.1.1
KCP 7.1.5		31/07/1998	Acute eye irritation/corrosion in the rabbit. Report No. 983063 Document No. VV-376069 , CGA173506/1169 Test Facility GLP Unpublished	Y	N	Expired	SYN	Y KIIIA 7.1.1
KCP 7.1.6		31/07/1998	Skin sensitization in the Guinea pig. Report No. 983064 Document No. VV-376070 , CGA173506/1170 Test Facility GLP Unpublished	Y	N	Expired	SYN	Y KIIIA 7.1.1
KCP 7.2.1.1		23/02/2009	Fluquinconazole and Prochloraz: Determination of Operator Exposure During Cereal Seed Treatment with "Jockey" Fungicide in Germany, United Kingdom and France. Report No. ACI07-006 Document No. VV-393832 , ASF827_10000 Test Facility Agrochemex International Ltd. GLP Unpublished	N	N	Expired	Seed Tropex Group (SYN access)	Y KIIIA 7.2.1.1

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 7.2.1.1	██████	21/09/2006	Determination of Operator Exposure to Imidacloprid during Treatment of Sugar Beet Seeds with IMPRIMO in France Report No. 04B033 HI Document No. VV-379857 , ASF654/0001 Test Facility RHODIA Recherches et Technologies GLP Unpublished	N	Y	Eligible for data protection according to SAN-CO/12576/2012; dependent on national product registration status	Seed Tropex Group (SYN access)	Y KIIIA 7.2.1.1
KCP 7.2.1.1	██████	2007	Determination of operator exposure to imidacloprid during loading/sowing of GAUCHO treated maize seeds under realistic field conditions in Germany and Italy Syngenta Crop Protection AG, Basel, Switzerland , IF-05/00328969 GLP not published Syngenta File No ASF654/0002	N	Y	Eligible for data protection according to SAN-CO/12576/2012; dependent on national product registration status	Seed Tropex Group (SYN access)	Y KIIIA 7.2.1.1
KCP 7.3	██████	22/10/2015	Fludioxonil/Metalaxyl-M/Cymoxanil WG (A9873C) - The In Vitro Percutaneous Absorption of Radiolabelled Metalaxyl-M and Radiolabelled Cymoxanil in a Concentrate Through Human Split thickness Skin Report No. 36500 Document No. VV-414733 , A9873C_10365 Test Facility Charles River Laboratories GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 9.1.1	██████	10/03/2015	Metalaxyl-M - Calculation of the formation fraction of the soil degradate CGA108906 for use in environmental models Report No. RAJ1079B Document No. VV-629108 , CGA329351_11688 Test Facility Syngenta - Jealott's Hill Not GLP	N	N	-	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?
			Unpublished					
KCP 9.1.1	██████	07/02/2020	CGA108906 – Kinetic evaluation of Formation Fraction Report No. RAJ1329B VV-862458 Document No. VV-742439 Test Facility Syngenta, Ltd. Not GLP Unpublished	N	N	-	SYN	N
KCP 9.1.2.3	██████ ██████	24/02/2020	Metalaxyl-M - Groundwater Monitoring Study in Portugal Report No. AUK-045-INT2 Document No. VV-244515 , CGA329351_11865 Test Facility Arcadis (UK) Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 9.2.4	██████████ ██████████ ██	16/12/2015	Metalaxyl-M - A Leaching Assessment for Metalaxyl-M and Its Soil Metabolites NOA409045, SYN546520 and CGA67868 Using the FOCUS-MACRO 5.5.4 Groundwater Model Following Seed Treatment to Sugar Beet in Sweden Report No. R1520297-20 Document No. VV-629801 , CGA329351_11727 Test Facility RIFcon GmbH Not GLP Unpublished	N	N	-	SYN	N
KCP 9.2.4	██████	06/04/2020	Cymoxanil - A Leaching Assessment for Cymoxanil and its Soil Metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Peas in the EU Report No. R1520325-5	N	N	-	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?
			Document No. VV-631545 , ASF331_10016 Test Facility RIFcon GmbH Not GLP Unpublished					
KCP 9.2.4		06/04/2020	Cymoxanil - A Leaching Assessment for Cymoxanil and its Soil Metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 Using the FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and FOCUS-MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Beans in the EU Report No. R1520325-9 Document No. VV-629643 , ASF331_10009 Test Facility RIFcon GmbH Not GLP Unpublished	N	N	-	SYN	N
KCP 9.2.4		06/04/2020	Fludioxonil - A Leaching Assessment for Fludioxonil Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Peas in the EU Report No. R1520325-2 Document No. VV-631541 , CGA173506_12279 Test Facility RIFcon GmbH Not GLP Unpublished	N	N	-	SYN	N
KCP 9.2.4		06/04/2020	Fludioxonil - A Leaching Assessment for Fludioxonil Using the FOCUS-PEARL 4.4.4, FOCUS-PELMO 5.5.3 and FOCUS-MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Beans in the EU Report No. R1520325-8 Document No. VV-629642 , CGA173506_11938 Test Facility RIFcon GmbH Not GLP	N	N	-	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?
			Unpublished					
KCP 9.2.4		06/04/2020	Metalaxyl-M A Leaching Assessment for Metalaxyl-M and its Soil Metabolites NOA409045, SYN546520 and CGA67868 Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Peas in the EU Report No. R1520325-1 Document No. VV-631540 , CGA329351_11831 Test Facility RIFcon GmbH GLP Unpublished	N	N	-	SYN	N
KCP 9.2.5		24/03/2016	Metalaxyl-M - A European Environmental Fate Assessment for Metalaxyl-M and its Metabolite NOA409045 Using the FOCUS Surface Water Model at Steps 1 to 2 Following Seed Treatment Application to Beans in the EU Report No. R1520325-10 Document No. VV-631552 , CGA329351_11833 Test Facility RIFcon GmbH Not GLP Unpublished	N	N	-	SYN	N
KCP 9.2.5		24/03/2016	Metalaxyl-M - A European Environmental Fate Assessment for Metalaxyl-M and its Metabolite NOA409045 Using the FOCUS Surface Water Model at Steps 1 to 2 Following Seed Treatment Application to Peas in the EU Report No. R1520325-3 Document No. VV-631542 , CGA329351_11832 Test Facility RIFcon GmbH Not GLP Unpublished	N	N	-	SYN	N
KCP		08/04/2020	Cymoxanil - A European Environmental Fate Assess-	N	N	-	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?
9.2.5			ment for Cymoxanil and its Metabolites IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533 and M5 Using the FOCUS Surface Water Model at Steps 1 to 2 Following Seed Treatment Application to Peas in the EU Report No. R1520325-6 Document No. VV-631546 , ASF331_10017 Test Facility RIFcon GmbH Not GLP Unpublished					
KCP 9.2.5		08/04/2020	Cymoxanil - A European Environmental Fate Assessment for Cymoxanil and its Metabolites IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533 and M5 Using the FOCUS Surface Water Model at Steps 1 to 2 Following Seed Treatment Application to Beans in the EU Report No. R1520325-12 Document No. VV-631560 , ASF331_10018 Test Facility RIFcon GmbH Not GLP Unpublished	N	N	-	SYN	N
KCP 9.2.5		25/05/2020	Fludioxonil - A European Environmental Fate Assessment for Fludioxonil and Its Metabolites CGA339833 and CGA192155 Using the FOCUS Surface Water Model at Steps 1-2 Following Seed Treatment Application to Peas in the EU Report No. R1520325-4 Document No. VV-631543 , CGA173506_12280 Test Facility RIFcon GmbH Not GLP Unpublished	N	N	-	SYN	N
KCP 9.2.5		25/05/2020	Fludioxonil - A European Environmental Fate Assessment for Fludioxonil and Its Metabolites	N	N	-	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?
			CGA339833 and CGA192155 Using the FOCUS Surface Water Model at Steps 1-2 Following Seed Treatment Application to Beans in the EU Report No. R1520325-11 Document No. VV-631553 , CGA173506_12281 Test Facility RIFcon GmbH Not GLP Unpublished					
KCP 9.2.5		25/06/2020	Cymoxanil - A European Environmental Fate Assessment for Cymoxanil Using the MACRO Drainflow Tool for UK Surface Water Calculations Following Seed Treatment Application to Peas Report No. R2060005-7 Document No. VV-863863 Test Facility RIFcon GmbH Not GLP Unpublished	N	N	-	SYN	N
KCP 10.1.1		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 GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 10.1.1		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 GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 10.1.1		07/05/1996	The reproductive toxicity test of CGA 24705 in Northern Bobwhite (Colinus virginianus)	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?
			Report No. 029508 Document No. VV-371001 , CGA24705/2591 Test Facility GLP Unpublished					
KCP 10.1.1		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 GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 10.1.1.2		12/03/2018	PT of woodpigeons in pre- and post-emergence maize fields in Germany, central zone (2017) Report No. P16052 Document No. VV-470595 , NA_14734 Test Facility GLP Unpublished	Y	N	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	SYN	Y KIIIA 10.1
KCP 10.1.1.2		01/08/2018	Determination of crop-specific growth dilution factors under semi-field conditions conditions for use in risk assessment of pesticide seed treatments for birds and mammals Report No. RF17/018 Document No. VV-546287 , NA_14735 Test Facility Bayer Crop Science AG Not GLP Unpublished	N	N	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	SYN	Y KIIIA 10.1
KCP 10.1.1.2		31/12/2006	Bird species in pea fields in Brittany (Northern France) - Field data for determination of focal species Report No. RA05225-1 T001019-06 Document No. VV-379792 , N/1085 Test Facility Rifcon	N	N	-	SYN	Y KIIIA 10.1

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?
			Not GLP Unpublished					
KCP 10.1.1.2	██████████ ██████████ ██████████	31/12/2006	Bird species in bean fields in Brittany (Northern France) - Field data for determination of focal species Report No. RA05225-2 T001019-06 Document No. VV-379790 , N/1086 Test Facility Rifcon Not GLP Unpublished	N	N	-	SYN	Y KIIIA 10.1
KCP 10.1.1.2	██████████ ██████████	23/12/2010	Exposure to birds in maize fields in France – Attractiveness of maize fields, relevant species, diet composition and portion to time. Report No. ██████████ Document No. VV-393540 , NA_11990 Test Facility ██████████ GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 10.1.1.2	██████████	28/09/2012	Fludioxonil, Thiabendazole, Azoxystrobin and Metaxyl-M - Dissipation of residues on treated maize seed and shoots Syngenta The Food and Environment Research Agency (Fera), Sand Hutton, UK, V7YG 1000 GLP not published Syngenta File No A14918E_10216, VV-402718	N	Y	New study never submitted before to this country	SYN	N
KCP 10.1.1.2	██████████	05/06/2014	Dissipation of fludioxonil, penflufen and prothioconazole on wheat seeds and seedlings in Germany Report No. B13017-2 Document No. VV-117164 , CGA173506_12044 Test Facility Bayer Crop Science AG GLP Unpublished	N	N	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	SYN	Y KIIIA 10.1

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 10.1.1.2	██████████	14/09/1999	Migration of Metalaxyl-M in Soil after Seed Treatment with [Phenyl-(U)-14C] CGA 329351 Report No. 98SV04 Document No. VV-312789 , CGA329351/1151 Test Facility Novartis Crop Protection AG GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.1.1.2	██████████ ██████	08/10/2014	Generic field study on small mammals - focal species and wood mouse (Apodemus sylvaticus) PT in maize fields in Germany Report No. ██████████ Document No. VV-406482 , NA_13410 Test Facility ██████████ GLP Unpublished	Y	N	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	SYN	Y KIIIA 10.1
KCP 10.1.1.2	██████	20/01/2005	Generic field monitoring of birds and mammals on maize and beet fields in Austria Report No. ██████████ Document No. VV-380792 , N/1155 Test Facility ██████████ GLP Unpublished	Y	N	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	SYN	Y KIIIA 10.1
KCP 10.1.2.1	██████████	04/08/1998	Acute dermal toxicity in the rat. Report No. 983061 Document No. VV-376067 , CGA173506/1167 Test Facility ██████████ GLP Unpublished	Y	N	Expired	SYN	N
KCP 10.2.1	██████████	20/11/1998	Testing of toxic effects of CGA 173506 + CGA 329351 + Cymoxanil WG 32.5 (A - 9873 C) on the single cell green alga Scenedesmus subspicatus Report No. 98208/01-AASS Document No. VV-312765 , CGA173506/1253	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?
			Test Facility GAB Biotechnologie GmbH GLP Unpublished					
KCP 10.2.1		26/11/1998	Acute toxicity testing of CGA 173506 + CGA 329351 + Cymoxanil WG 32.5 (A - 9873 C) in Rainbow trout (<i>Oncorhynchus mykiss</i>) Teleostei, Salmonidae) Report No. Document No. VV-312787 , CGA173506/1255 Test Facility GLP Unpublished	Y	N	Expired	SYN	N
KCP 10.2.1		26/11/1998	Assessment of toxic effects of CGA 173506 + CGA 329351 + Cymoxanil WG 32.5 (A - 9873 C) on <i>Daphnia magna</i> using the 48h acute immobilisation test Report No. 98208/01-AADM Document No. VV-312764 , CGA173506/1256 Test Facility GAB Biotechnologie GmbH GLP Unpublished	N	N	Expired	SYN	N
KCP 10.3.1.1		16/04/2013	Metalaxyl-M/Cymoxanil/Fludioxonil WG (A9873C) - Acute Oral and Contact Toxicity to the Honeybee <i>Apis mellifera</i> L. (Hymenoptera, Apidae) under Laboratory Conditions Report No. S13-00121 Document No. VV-404485 , A9873C_10224 Test Facility Eurofins Agrosience Services EcoChem GmbH GLP Unpublished	N	N	Expired	SYN	N
KCP 10.3.2.1		14/12/1998	CGA 173506 + CGA 329351 + Cymoxanil WG 32.5 (A - 9873 C): acute toxicity to the staphylinid beetle, <i>aleochara bilineata</i> Gyll. (Coleoptera, Staphylinidae) in the laboratory	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?
			Report No. 98310/01-NLAB Document No. VV-312681 , CGA173506/1279 Test Facility GAB Biotechnologie GmbH GLP Unpublished					
KCP 10.3.2.1		14/12/1998	CGA 173506 + CGA 329351 + Cymoxanil WG 32.5 (A - 9873 C): acute toxicity to the ground beetle, poecilus cupreus L. (Coleoptera, Carabidae) in the laboratory Report No. 98310/01-NLPC Document No. VV-312682 , CGA173506/1280 Test Facility GAB Biotechnologie GmbH GLP Unpublished	N	N	Expired	SYN	N
KCP 10.3.2.2		24/09/2014	Metalaxyl-M/Cymoxanil/Fludioxonil WG (A9873C) – A rate-response extended laboratory bioassay of the effects of fresh residues on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) Report No. SYN-14-59 Document No. VV-410136 , A9873C_10340 Test Facility Mambo-Tox Ltd. GLP Unpublished	N	N	Expired	SYN	N
KCP 10.3.2.2		04/01/2019	Metalaxyl-M/Cymoxanil/Fludioxonil WG (A9873C) - A rate-response extended laboratory test to evaluate the effects of fresh residues on the predatory bug Orius laevigatus (Heteroptera; Anthrenidae) Report No. SYN-18-64 Document No. VV-470950 , A9873C_10480 Test Facility Mambo-Tox Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP		12/09/2014	Metalaxyl-M/Cymoxanil/Fludioxonil WG (A9873C) –	N	N	Expired	SYN	Y

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?
10.3.2.2			A rate-response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp <i>Aphidius rhopalosiphii</i> (Hymenoptera, Braconidae) Report No. SYN-14-58 Document No. VV-410137 , A9873C_10341 Test Facility Mambo-Tox Ltd. GLP Unpublished					KIIIA 10.5.1
KCP 10.3.2.2		31/01/2019	Metalaxyl-M/Cymoxanil/Fludioxonil WG (A9873C) - A rate-response extended laboratory bioassay of the effects of fresh residues on the rove beetle, <i>Aleochara bilineata</i> (Coleoptera : Staphylinidae) Report No. SYN-18-65 Document No. VV-471369 , A9873C_10483 Test Facility Mambo-Tox Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.4.1.1		28/03/2019	Fludioxonil/Metalaxyl-M/Cymoxanil WG (A9873C) - Sublethal Effects on the Reproduction of the Earthworm <i>Eisenia andrei</i> in Artificial Soil Report No. 19 48 TEC 0012 Document No. VV-471833 , A9873C_10488 Test Facility BioChem agrar GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.4.1.1		11/11/1998	Assessment of sub lethal effects of CGA 173506 + CGA 329351 + Cymoxanil WG 32.5 (A - 9873 C) on <i>Eisenia foetida</i> in artificial soil (determination of effects on reproduction) Report No. 98310/01-NREF Document No. VV-312766 , CGA173506/1252 Test Facility GAB Biotechnologie GmbH GLP	N	N	Expired	SYN	Y KIIIA 10.6.1.2

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?
			Unpublished					
KCP 10.4.2.1		06/08/2004	CGA329351, CGA173506, cymoxanil: Toxicity of WAKIL XL WG 32.5 (A9873C) on the reproduction of the Collembolans Folsomia candida Report No. 04 10 48 075 Document No. VV-334131 , CGA329351/1928 CGA173506/5971 Test Facility BioChem agrar GLP Unpublished	N	N	Expired	SYN	Y KIIIA 10.6.2
KCP 10.4.2.1		23/01/2015	Metalaxyl-M/Cymoxanil/Fludioxonil WG (A9873C) – A laboratory test to determine the effects of fresh residues on the predatory mite Hypoaspis aculeifer (Acari, Laelapidae) Report No. SYN-14-104 Document No. VV-411295 , A9873C_10349 Test Facility Mambo-Tox Ltd. GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 10.5		25/11/2014	Metalaxyl-M/Cymoxanil/Fludioxonil WG (A9873C) – Effect on Soil Microbial Activity, Carbon and Nitrogen Transformations Report No. CEMR-6658 Document No. VV-411156 , A9873C_10345 Test Facility CEMAS GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 5.4.2		08/06/2015	NOA409045 - Oral (Gavage) Mouse Micronucleus Test Report No. Document No. VV-28599 , NOA409045_10012 Test Facility GLP	Y	Y	New study never submitted before to this country		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?
			Unpublished					
KCA1 5.4.2		15/09/2017	CGA226048 - Oral (Gavage) Mouse Micronucleus Test Report No. Document No. VV-468462 , CGA226048_10000 Test Facility GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCA1 6.1		10/09/2018	Cymoxanil (ASF331) – Storage Stability of Residues of Cymoxanil in Crop Matrices Stored Frozen for up to Two Years Report No. RES-00069 Document No. VV-470684 , ASF331_10019 Test Facility ResChem Analytical Limited GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Met-alaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2010/98 Document No. VV-312513 , CGA173506/4962 Test Facility Novartis Crop Protection AG GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Met-alaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2011/98 Document No. VV-312406 , CGA173506/4963 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	ETL_blank	Y KIIA 6.3
KCA1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Met-	N	N	Expired	ETL_blank	Y

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?
6.3.1			alaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV-312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP Unpublished					KIIA 6.3
KCA1 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Met-alaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2013/98 Document No. VV-312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Met-alaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2014/98 Document No. VV-312409 , CGA173506/4966 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Met-alaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV-312410 , CGA173506/4967 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.1		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Met-alaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in	N	N	Expired	SYN	Y

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?
			or on Peas in France (North) Report No. 0140501 Document No. VV-330998 , CGA173506/5506 Test Facility ADME - Bioanalyses GLP Unpublished					KIIA 6.3
KCA1 6.3.1		30/06/2003	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV-328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.1		01/08/2003	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV-340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.2		10/12/1998	Residue Study with Metalaxyl-M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2296/97 Document No. VV-312761 , CGA173506/1259 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.2		10/12/1998	Residue Study with Metalaxyl-M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North).	N	N	Expired	SYN	Y KIIA 6.3

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?
			Report No. 2297/97 Document No. VV-312760 , CGA173506/1260 Test Facility Novartis Crop Protection AG GLP Unpublished					
KCA1 6.3.2		10/12/1998	Residue study with Metalaxyl-M (CGA329351, Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2298/97 Document No. VV-312758 , CGA173506/1261 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.2		10/12/1998	Residue Study with Metalaxyl-M (CGA329352), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2299/97 Document No. VV-312759 , CGA173506/1262 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.2		07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom Report No. 2008/98 Document No. VV-312762 , CGA173506/4968 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.2		07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom Report No. 2009/98	N	N	Expired	SYN	Y KIIA 6.3

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?
			Document No. VV-312763 , CGA173506/4969 Test Facility Novartis Crop Protection AG GLP Unpublished					
KCA1 6.3.2		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV-330998 , CGA173506/5506 Test Facility ADME - Bioanalyses GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.2		30/06/2003	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV-328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 6.3.2		01/08/2003	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV-340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA1 7.1.2.1		2010	¹⁴ C-IN-KQ960: Rate of Degradation in Five Soils. DuPont-28466. E.I. du Pont de Nemours and Company, Wilmington, DE, U.S.A Document Number: DuPont-28466	N	N	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	(SYN access)	Y KIIIA 10.1

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 7.1.3.1	██████	2010	¹⁴ C-IN-KQ960: Batch Equilibrium (Adsorption/Desorption) in Five Soils. DuPont-28467. E. I. du Pont de Nemours and Company, Wilmington, DE, U.S.A. Document Number: DuPont-28467	N	N	Syngenta reached agreement with the data owner to access the study. Data owner to provide further details directly if required	(SYN access)	Y KIIIA 10.1
KCA2 6.3.1	██████	20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2011/98 Document No. VV-312406 , CGA173506/4963 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.1	██████	20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV-312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.1	██████	20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2013/98 Document No. VV-312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.1	██████	20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF	N	N	Expired	SYN	Y

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?
			331) in or on Peas in France (South) Report No. 2014/98 Document No. VV-312409 , CGA173506/4966 Test Facility Novartis Crop Protection AG GLP Unpublished					KIIA 6.3
KCA2 6.3.1		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV-312410 , CGA173506/4967 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.1		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV-330998 , CGA173506/5506 Test Facility ADME - Bioanalyses GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.1		30/06/2003	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV-328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.1		01/08/2003	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002	N	N	Expired	SYN	Y KIIA 6.3

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?
			Report No. gpe514002 Document No. VV-340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished					
KCA2 6.3.2		10/12/1998	Residue Study with Metalaxyl-M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2296/97 Document No. VV-312761 , CGA173506/1259 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.2		10/12/1998	Residue Study with Metalaxyl-M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2297/97 Document No. VV-312760 , CGA173506/1260 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.2		10/12/1998	Residue study with Metalaxyl-M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2298/97 Document No. VV-312758 , CGA173506/1261 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.2		10/12/1998	Residue Study with Metalaxyl-M (CGA329352), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2299/97	N	N	Expired	SYN	Y KIIA 6.3

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?
			Document No. VV-312759 , CGA173506/1262 Test Facility Novartis Crop Protection AG GLP Unpublished					
KCA2 6.3.2		07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom Report No. 2008/98 Document No. VV-312762 , CGA173506/4968 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.2		07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom Report No. 2009/98 Document No. VV-312763 , CGA173506/4969 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.2		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV-330998 , CGA173506/5506 Test Facility ADME - Bioanalyses GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 6.3.2		01/08/2003	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV-340015 , CGA173506/5765	N	N	Expired	SYN	Y KIIA 6.3

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?
			Test Facility Syngenta Agro GmbH GLP Unpublished					
KCA2 6.3.2		30/06/2003	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV-328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA2 7.1.2.2.1		06/09/2004	Fludioxonil : Field Study Comparing Seed Treatment Dissipation Against Field Dissipation in Switzerland During 2003 Report No. RJ3547B Document No. VV-330403 , CGA173506/5993 Test Facility Syngenta - Jealott's Hill GLP Unpublished	N	N	Expired	SYN	Y KIIA 7.1.1.2.2
KCA2 8.1.1.1		30/09/2015	Fludioxonil - A Reproduction Study with the Northern Bobwhite Report No. 528B-457 Document No. VV-511362 , CGA173506_51544 Test Facility Wildlife International Ltd. GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCA2 8.2.2.2		23/07/2015	Fludioxonil - Full Life-Cycle Toxicity Test with Fathead Minnow (Pimephales promelas) Following FIFRA Guideline 72-5 and OCSPP Draft Guideline 850.1500 Report No. 1781.6971 Document No. VV-511038 , CGA173506_51494 Test Facility Smithers Viscient	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?
			GLP Unpublished					
KCA2 8.2.5.1		28/03/2014	Fludioxonil - Full Life-Cycle Toxicity Test with Water Fleas, Daphnia magna, Under Static Renewal Conditions Report No. 1781.6936 Document No. VV-411343 , CGA173506_51057 Test Facility Smithers Viscient GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA2 8.3.1.2		20/11/2014	Fludioxonil FS (A8207M) – Honeybee (Apis mellifera L.) Chronic Feeding Study Report No. S023AMCP Document No. VV-410994 , A8207M_10357 Test Facility MITOX Consultants GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA2 8.3.1.3		25/02/2020	Fludioxonil FS (A8207M) – Statistical Re-analysis - Fludioxonil FS (A8207M) – Honey bee (Apis mellifera L.) Larval Toxicity Test (Repeated Exposure) Report No. CEA.2135 Document No. VV-748040 Test Facility IBACON GmbH Not GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA2 8.3.1.3		07/12/2015	Fludioxonil FS (A8207M) - Honey bee (Apis mellifera L.) Larval Toxicity Test (Repeated Exposure) Report No. S15-02449 Document No. VV-415016 , A8207M_10595 Test Facility Eurofins Agrosience Services EcoChem GmbH	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?
			GLP Unpublished					
KCA2 8.4.2		23/02/2015	Fludioxonil FS (A8207M) – Effects on the Reproduction of the Predatory Mite Hypoaspis aculeifer Report No. 15 10 48 010 S Document No. VV-411591 , A8207M_10371 Test Facility BioChem agrar GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA3 6.3.1		17/09/2001	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2016/00 Document No. VV-318292 , CGA329351/1534 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.1		17/09/2001	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2017/00 Document No. VV-318288 , CGA329351/1533 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.1		17/09/2001	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on BroadBeans in France (North) Report No. 2114/00 Document No. VV-318171 , CGA329351/1525 Test Facility Syngenta Crop Protection AG GLP	N	N	Expired	SYN	Y KIIA 6.3

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?
			Unpublished					
KCA3 6.3.1		17/09/2001	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on BroadBeans in France (North) Report No. 2115/00 Document No. VV-318174 , CGA329351/1526 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.1		31/05/2002	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in United Kingdom Report No. 2093/01 Document No. VV-332793 , CGA329351/1580 Test Facility ADME - Bioanalyses GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.1		31/05/2002	Residue Study with Metalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in United Kingdom Report No. 2094/01 Document No. VV-332794 , CGA329351/1579 Test Facility ADME - Bioanalyses GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2010/98 Document No. VV-312513 , CGA173506/4962 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3

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?
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 2011/98 Document No. VV-312406 , CGA173506/4963 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2013/98 Document No. VV-312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2014/98 Document No. VV-312409 , CGA173506/4966 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.2		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV-312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3		20/05/1999	Residue Study with Fludioxonil (CGA 173506),	N	N	Expired	SYN	Y

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?
6.3.2			Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV-312410 , CGA173506/4967 Test Facility Novartis Crop Protection AG GLP Unpublished					KIIA 6.3
KCA3 6.3.2		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501 Document No. VV-330998 , CGA173506/5506 Test Facility ADME - Bioanalyses GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.2		30/06/2003	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV-328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.2		01/08/2003	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV-340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.2		02/03/1998	Determination of Residues of CGA329351 in Peas. Report No. GR 31197	N	N	Expired	SYN	Y

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?
			Document No. VV-376072 , CGA329351/0797 Test Facility Novartis Agro GmbH GLP Unpublished					KIIA 6.3
KCA3 6.3.3		10/12/1998	Residue Study with Metalaxyl-M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2296/97 Document No. VV-312761 , CGA173506/1259 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		10/12/1998	Residue Study with Metalaxyl-M (CGA329351), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in France (North). Report No. 2297/97 Document No. VV-312760 , CGA173506/1260 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		10/12/1998	Residue study with Metalaxyl-M (CGA329351, Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2298/97 Document No. VV-312758 , CGA173506/1261 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		06/03/1998	Magnitude of Residues of CGA329351 in Peas after Sowing Seed Treated with Formulation ES 350 (A-9642 C) in the Netherlands at one Site. Report No. 140/97 Document No. VV-376071 , CGA329351/0793	N	N	Expired	SYN	Y KIIA 6.3

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?
			Test Facility Novartis Crop Protection AG GLP Unpublished					
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2012/98 Document No. VV-312407 , CGA173506/4964 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2015/98 Document No. VV-312410 , CGA173506/4967 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		10/12/1998	Residue Study with Metalaxyl-M (CGA329352), Fludioxonil (CGA173506) and Cymoxanil (ASF331) in or on Peas in the United Kingdom. Report No. 2299/97 Document No. VV-312759 , CGA173506/1262 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		07/06/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in United Kingdom Report No. 2008/98 Document No. VV-312762 , CGA173506/4968 Test Facility Novartis Crop Protection AG	N	N	Expired	SYN	Y KIIA 6.3

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?
			GLP Unpublished					
KCA3 6.3.3		10/11/1999	Residue Study with Metalaxyl-M (CGA 329351) in or on Peas in Netherlands Report No. 2153/98 Document No. VV-309632 , CGA329351/1193 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		06/03/1998	CGA 329351, ES 350, A-9642 C, Beans, The Netherlands Report No. 141/97 Document No. VV-357034 , CGA329351/0792 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		06/03/1998	CGA 329351, ES 350, A-9642 C, Peas (empty pods, seeds), Spain Report No. 2003/97 Document No. VV-357039 , CGA329351/0795 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		06/03/1998	CGA 329351, ES 350, A-9642 C, Peas (pods, with seed), Spain Report No. 2004/97 Document No. VV-357042 , CGA329351/0796 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South)	N	N	Expired	SYN	Y KIIA 6.3

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?
			Report No. 2013/98 Document No. VV-312408 , CGA173506/4965 Test Facility Novartis Crop Protection AG GLP Unpublished					
KCA3 6.3.3		20/05/1999	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (South) Report No. 2014/98 Document No. VV-312409 , CGA173506/4966 Test Facility Novartis Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		12/08/2002	Residue Study with Methalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2008/01 Document No. VV-332796 , CGA329351/1616 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		12/08/2002	Residue Study with Methalaxyl-M (CGA 329351) and Chlorothalonil (ASF 41) in or on Broad Beans in Switzerland Report No. 2009/01 Document No. VV-332797 , CGA329351/1617 Test Facility Syngenta Crop Protection AG GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		07/08/2002	Residue Study with Fludioxonil (CGA 173506), Metalaxyl-M (CGA 329351) and Cymoxanil (ASF 331) in or on Peas in France (North) Report No. 0140501	N	N	Expired	SYN	Y KIIA 6.3

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?
			Document No. VV-330998 , CGA173506/5506 Test Facility ADME - Bioanalyses GLP Unpublished					
KCA3 6.3.3		30/06/2003	Determination of Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL in Peas in Germany (2001) Report No. gpe14201 Document No. VV-328561 , CGA173506/5666 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		01/08/2003	Residues of Metalaxyl-M, Fludioxonil and Cymoxanil after seed treatment with WAKIL XL (A9873C) in Peas, Germany 2002 Report No. gpe514002 Document No. VV-340015 , CGA173506/5765 Test Facility Syngenta Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		02/03/1998	Determination of Residues of CGA329351 in Peas. Report No. GR 31197 Document No. VV-376072 , CGA329351/0797 Test Facility Novartis Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3 6.3.3		02/03/1998	Determination of Residues of CGA329351 in Peas. Report No. GR 32297 Document No. VV-376073 , CGA329351/0798 Test Facility Novartis Agro GmbH GLP Unpublished	N	N	Expired	SYN	Y KIIA 6.3
KCA3		26/06/1998	CGA 329351, ES 350, A-9642 C, Beans, Germany	N	N	Expired	SYN	Y

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?
6.3.3			Report No. GR 35297 Document No. VV-357457 , CGA329351/0934 Test Facility Novartis Agro GmbH GLP Unpublished					KIIA 6.3
KCA3 8.3.1.1		06/06/2017	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	New study never submitted before to this country	SYN	N
KCA3 8.3.1.3		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	New study never submitted before to this country	SYN	N

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA1 5.4.2		12/08/2014	CGA62826 - Oral (Gavage) Mouse Micronucleus Test Report No. Document No. VV-410510 , CGA062826_10006 Test Facility GLP Unpublished	Y	N	Expired	SYN
KCA1 5.4.2		27/01/2015	Metalaxyl-M - Oral (Gavage) Mouse Micronucleus Test Report No. Document No. VV-411540 , CGA329351_11683 Test Facility GLP Unpublished	Y	Y	New study never submitted before to this country	SYN