DRAFT REGISTRATION REPORT

Part A

Risk Management

Product code: A20607B

Product name(s): VIBRANCE SB

Chemical active substances:

Fludioxonil, 22.5 g/L
Metalaxyl-M, 14.4 g/L
Sedaxane, 15 g/L

~~United Kingdom~~

Great Britain (GB)

NATIONAL ASSESSMENT

~~(Renewal of authorization)~~

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

Applicant: Syngenta

Submission date: ~~01/09/2020~~ 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
January 2023	HSE (GB) assessment added in green boxes

This is an application from Syngenta for the renewal of VIBRANCE SB (A20607B) 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 VIBRANCE SB (A20607B) 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 VIBRANCE SB (A20607B) 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.

Table of Contents

PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Syngenta. Germany was the zRMS for the evaluation.

The application was for approval of VIBRANCE SB (A20607B), a FS formulation containing 22.5 g/L fludioxonil, 14.4 g/L metalaxyl-M and 15 g/L sedaxane for use as a fungicide seed treatment on diverse crops (see details of intended uses on paragraph 2.6 of this document).

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 (metalaxyl-M) and Regulation 283/2013 (sedaxane, fludioxonil) and the data requirements for the plant protection product laid down in Regulation (EC) 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.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	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). 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 published[1]. The renewal of metalaxyl-M applies since 1 June 2020. Since this was before 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 15.0. g/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.

[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 plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

	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".

1.2 Letters of Access

Not applicable.

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 A20607B, 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	A20607B
Product name in MS	VIBRANCE SB
Authorization number	MAPP 18588
Function	Fungicide
Applicant	Syngenta UK Ltd.
Active substance(s) (incl. content)	Fludioxonil, 22.5 g/L Metalaxyl-M; 14.4 g/L Sedaxane, 15 g/L
Formulation type	Flowable concentrate for seed treatment [FS]
Packaging	Professional user 10 L, 20 L HDPE canister 50 L, 200L HDPE drum 500 L, 1000 L HDPE RIBC container
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identiy	Not applicable
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

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:	Chronic aquatic toxicity, Category 2

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	
Signal word:	n.a.
Hazard statement(s):	**H411** Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	**Response:** **P391** Collect spillage **Disposal:** **P501** Dispose of contents/ container to an approved waste disposal plant.
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction . **[EUH208]**

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. **[EUH401]**
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction . **[EUH208]**

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	Toxicology: Based on the information available, the formulated product A20607B meets the criteria for classification for the following human health hazard in accordance with Regulation 1272/2008 (CLP): **Carcinogenicity Category 2 (H351)** The following label elements should be used with respect to human health:

Hazard class(es), categories	**Carc. Cat. 2; H351**
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS08
Signal word	Warning

Hazard statement(s)	Suspected of causing cancer
Precautionary Statements triggered by human health hazard classification P280 Wear protective gloves/protctive clothing/eye protection/face protection P308 + P313 IF exposed or concerned: Get medical advice/attention.	
EUH208	**‘**Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction.’

In addition to the human health hazard classifications, the label needs to include the additional labelling EUH208 **‘**Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction.’ (See dRR Part C for details).

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, coverall, half-face mask and safety spectacles.
Worker protection:	
None	Gloves when loading the 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)

GAP rev. 1, date: 2020-09-01

PPP (product name/code):	VIBRANCE SB / A20607B	Formulation type:	FS [a, b]
Active substance 1:	Fludioxonil	Conc. of a.s. 1:	22.5 g/L [c]
Active substance 2:	Metalaxyl-M	Conc. of a.s. 2:	14.4 g/L [c]
Active substance 3:	Sedaxane	Conc. of a.s. 3:	15 g/L [c]
Safener:	safener	Conc. of safener:	n/a [c]
Synergist:	synergist	Conc. of synergist:	n/a [c]
Applicant:	Syngenta	Professional use:	☒
Zone(s):	Interzonal [d]	Non professional use:	☐
Verified by MS:	yes/no		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	10a	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**				**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	ml product / seed unit	Max g a.s./100 kg seeds 1) Fludioxonil 2) Metalaxyl-M 3) Sedaxane	Max g a.s./ha 1) Fludioxonil 2) Metalaxyl-M 3) Sedaxane	Max µg a.s./seed 1) Fludioxonil 2) Metalaxyl-M 3) Sedaxane		e.g. g safener/synergist per ha [f]
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)														
10	United Kingdom	Beet (Sugar (BEAVA) and fodder (BEAVC) beet)	I	Damping-off diseases (*Pythium ultimum* [PYTHUL], *Pleospora betae/P betae* [PLEOBJ], *Thanatephorus cucumeris / Rhizoctonia solani* [RHIZSO])	Seed treatment	BBCH 00 Jan-Dec	1	n.a.	33.3	1) 31.22 2) 19.98 3) 20.81	1) 0.97 2) 0.62 3) 0.65	1) 7.49 2) 4.80 3) 5.00	n.a.	Seed unit: 100.000 seeds Seedling rate: 1 – 1.3 seed unit/ha TGW: 24-33 g/1000 seeds Slurry volume: 8-20L/100 kg seeds Max. 43.3 ml product/ha
			F		Sowing	BBCH 00 March-April								
			n.a.		Transplanting	n.a.								

Remarks table heading:

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

Remarks columns:

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

3 Background of authorization decision and risk management

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	Vibrance SB' was not the representative product for the approval of metalaxyl-M. 'Vibrance SB' has been assessed in the current evaluation as a representative product for the Article 7 amendment of the approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Vibrance SB' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and sedaxane have not been considered further. 'Vibrance SB' is a FS formulation containing 14.4 g/L metalaxyl-M, 15 g/L sedaxane and 22.5 g/L fludioxonil. The intended in-use concentration of product is 6% to 15%. 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. 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). 'Vibrance SB' is a light grey liquid. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 550 ± 55°C. The pH of the 1% dilution of the preparation is 6.7. Acceptable physical, chemical and technical data have been provided indicating that the product fulfils the requirements of a FS formulation. Acceptable accelerated (2 weeks at 54°C) storage stability data have been submitted indicating the product does retain its technical properties during storage. Data on the content of metalaxyl-M, sedaxane and fludioxonil before and after accelerated storage shows no significant degradation. 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 product containing metalaxyl-M. The applicant's case for CGA72649 and CGA 363736 was accepted. The applicant's 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 applicant's 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 'Vibrance SB', this case may not be accepted for future products. A low temperature storage stability data is required and has been submitted. An ambient shelf-life study has been submitted, conducted using product stored in HDPE. The data indicate the product does retain its technical properties during storage. Data on the content of metalaxyl-M, sedaxane 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 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 'A20607B' batch SMU4DP001 or SMU7AL007. This is the same composition as the proposed product "A20607B" **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 of the B1,2,4.

VIBRANCE SB (A20607B) is a flowable concentrate formulation (FS) 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 light grey liquid, with mild odour. It is not explosive, has no oxidising properties. The product is not a flammable liquid (flash point not detected below 101°C). It has a self-ignition temperature of 550 ± 55°C. In aqueous solution, it has a pH value around 6.7 at 25°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The ambient temperature shelf-life studies (two years at 20°C) show no significant changes in physical properties or content of active ingredients, and therefore the product A20607B will have a shelf-life of at least two years at ambient temperature. Its technical characteristics are acceptable for flowable concentrate for seed treatment formulation.

The intended concentration of use is 6% to 15%.

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 A20607B.

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 A20607B.

Compliance with FAO specifications:

There is no FAO specification for A20607B.

Formulation used for tests:

All physico-chemical endpoints were measured using A20607B. Thus, no bridging to other formulations

is required.

3.2 Efficacy (Part B, Section 3)

A20607B (VIBRANCE SB) is a flowable concentrate seed treatment (FS) containing 22.5 grams per litre (g/l) fludioxonil, 14.4 grams per litre (g/l) metalaxyl-M and 15.0 grams per litre (g/l) sedaxane for use on sugar beet for the control of *Phoma betae*, *Pythium ultimum* and *Thanatephorus cucumeris* (the telemorph of *Rhizoctonia solani*).

3.3 Efficacy data

There has been no GAP change that impacts the previous Efficacy evaluation of A20607B. 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

Fludioxonil

Fludioxonil blocks a protein kinase that catalyses phosphorylation of a regulatory enzyme of glycerol synthesis. This inhibits spore germination and growth of germ tubes and mycelia before penetration of the plant tissues. The mechanism of action is not fully resolved, however, mutations in the histidine kinase (Os-2 MAP kinase) involved in osmosensing mediate resistance to phenylpyrroles. Possibly also additional genes or mechanisms are involved. Phenylpyrrol fungicides as fludioxonil are classified as medium resistance risk.

Sedaxane

Sedaxane inhibits the spore germination, growth of mycelium and the sporulation of the pathogens. SDH inhibitors as sedaxane are estimated as medium to high risk compounds. Due to their unique mode of action and site of action, they show no cross resistance with other chemical classes such as strobilurines, benzimidazoles, anilinopyrimidines or demethylation inhibitors. However, due to the specificity of their mode of action, this group can potentially cause selection of resistance among the pathogen population in the field.

Metalaxyl-M

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 Phytophtora infestans and Peronospora spp. and FRAC characterizes the risk for resistance development as high, because of the single site mode of action. Metalaxyl-M is a member of the phenylamide (PA) fungicides which bear an intrinsically high resistance risk based on their single site mode of action (inhibition of r RNA polymerase complex I)

3.3.2 Adverse effects on treated crops

There has been no GAP change that impacts the previous Efficacy evaluation of A20607B. 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 A20607B. 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), UK**
Reviewer's comments	This application is for the amendment to the approval for metalaxyl-M under Article 7 of Regulation (EC) No 1107/2009. This is a GB application. 'Wakil XL' and 'Vibrance SB' have been assessed as representative products for the Article 7 amendment, no chemistry specific amendments have been assessed – only metalaxyl-M has been considered. The applicant has access to the data considered in the DAR/RAR for metalaxyl-M as they are the data owner. 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. Sufficiently validated analytical methods are available for: • 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 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. New data generation methods in support of support of efficacy, environmental fate, residues in plants, residues in animal products, and toxicology studies were not submitted and are not required. 2 additional methods were evaluated to support ecotoxicology studies; however, this was for dose verification only. Sufficiently validated analytical methods are available to allow monitoring of residues of metalaxyl-M in • 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

Analytical methods have been developed for the determination of Fludioxonil, Metalaxyl-M and Sedaxane in plant protection product A20607B. Full validation of methods ST-35/1 and STA-35/2 have been conducted. Analytical method ST-35/1 is suitable for the specific, accurate and precise determination of Sedaxane (stereoisomers SYN508210 and SYN508211), Fludioxonil and Metalaxyl-M (including the S-enantiomer) in product A20607B. Analytical method STA-35/2 is suitable for the specific, accurate and precise determination of Metalaxyl-M (CGA329351) and S-enantiomer (CGA351920) in product A20607B.

Fludioxonil and sedaxane 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 A20607B. The method is suitable for the specific, accurate and precise determination of CGA72649 and CGA363736 in product A20607B.

There are no relevant formulants in A20607B therefore no methods are required.

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

3.4.2 Analytical methods for residues

Pre- and post-authorisation analytical methods for of Fludioxonil, Metalaxyl-M and Sedaxane 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)

<table>
<tr><th colspan="7">EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY</th></tr>
<tr><td>Name of authority</td><td colspan="6">HSE Chemicals Regulation Division (CRD), UK</td></tr>
<tr><td>Reviewer's comments</td><td colspan="6">
<u>Toxicology:</u>

Human health hazard assessment
The applicant proposes to meet the data requirements for acute toxicity (oral, dermal and inhalation), skin and eye irritation and skin sensitisation using studies previously evaluated by HSE. The studies were accepted and evaluated under 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.

Based on the information available, the formulated product A20607B 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 sedaxane. Sedaxane is classified in Category 2 for carcinogenicity in accordance with the GB MCL Technical Report (2021). Sedaxane is present at 15 g/L or 1.45 % w/w in the product. In accordance with Regulation 1272/2008 (CLP), the generic concentration limit is ≥ 1 %; therefore the product should be classified for Carc. Cat. 2, H351. This classification was applied under the following zonal application.

Reference Values

The agreed toxicological reference values for metalaxyl-M are as follows:

<u>Metalaxyl-M (1.4% in product) (EFSA Journal 2015;13(3):3999)</u>

<table>
<tr><td>Classification</td><td colspan="5">Acute oral toxicity Category 4; H302, Serious eye damage Category 1; H318; EU CLH and GB MCL (mandatory classification)'</td></tr>
<tr><td>AOEL</td><td>0.08 mg/kg bw/d</td><td>NOAEL = 8 mg/kg bw/d</td><td>AF= 100</td><td>Dog RDT studies (90-day, 6-month, 1 &2-years)</td><td>Increases in liver weight and AP and ALT levels; anaemia</td></tr>
<tr><td>ADI</td><td>0.08 mg/kg bw/d</td><td>NOAEL = 8 mg/kg bw/d</td><td>AF= 100</td><td>Dog RDT studies (90-day, 6-month, 1 &2-years)</td><td>Increases in liver weight and AP and ALT levels; anaemia</td></tr>
<tr><td>ARfD</td><td>0.5 mg/kg bw</td><td>NOAEL = 50 mg/kg bw/d</td><td>AF= 100</td><td>Rat Developmental study</td><td>Mortality, clinical signs and decrease in bw gain</td></tr>
<tr><td>AAOEL</td><td>N/A</td><td>N/A</td><td>N/A</td><td>N/A</td><td>N/A</td></tr>
</table>
The agreed toxicological reference values for sedaxane are as follows:

<u>Sedaxane (1.45% in product) (EFSA Journal 2013;11(1):3057)</u>

<table>
<tr><td>Classification</td><td>Carc. 2; H351 (Suspected of causing cancer); EU CLH and GB MCL (mandatory classification)</td></tr>
</table>
</td></tr>
</table>

AOEL	0.28 mg/kg bw/d	NOAEL = 28 mg/kg bw/d	AF= 100	Rat 90-day study	Liver (increased weight), reduced foregrip strength (females)
ADI	0.11 mg/kg bw/d	NOAEL = 11 mg/kg bw/d	AF= 100	Rat 2-year study	Liver (hypertrophy, increased weight)/ thyroid follicular cell hypertrophy, baso-philia
ARfD	0.3 mg/kg bw	NOAEL = 30 mg/kg bw/d	AF= 100	Rat Acute neurotoxicity study	Reduced locomotor activity, decreased body weight, body weight gain, food consumption
AAOEL	N/A	N/A	N/A	N/A	N/A

The agreed toxicological reference values for fludioxonil are as follows:

Fludioxonil (2.2% 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 Vibrance SB (A20607B) has been evaluated as a representative use. As such, only the dermal absorption of metalaxyl-M has been evaluated.

The applicant proposes to meet the data requirements for dermal absorption by application of default dermal absorption values in accordance with Section 6.1 of the EFSA guidance on dermal absorption (2017).

A20607B is a flowable concentrate for seed treatment (FS); this formulation type falls under the formulation category of 'Water-based/dispersed'. Therefore, as the active sub-stance is present at <5% (in the concentrate), the default values of 50% for the concentrate is applicable. As the product is to be applied only as a concentrate, a dermal absorption

value for a dilution is not required.

The finalised dermal absorption values to be applied to A20607B are summarised below:

	Metalaxyl-M	
	Value (%)	**Reference**
Concentrate	50	Default values for FS formulation (EFSA Journal 2017; 15(6):4873)
Dilution	N/A	N/A

Groundwater metabolites – relevance assessment

No metabolites of metalaxyl-M are predicted to occur in groundwater at concentrations above 0.1 µg/L.

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 Vibrance SB (A20607B) 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 Vibrance SB (A20607B) has not been evaluated under the Article 7 evaluation.

3.5.1 Acute toxicity

A summary of the toxicological evaluation for A20607B is given in the following table:

Type of test, species, model system (Guideline)	**Result**	**ATE & Additivity Calculation Result**	**Acceptability**	**Classification [1] (acc. to the criteria in Reg. 1272/2008)**
LD_{50} oral, rat (OECD 425)	> 5000 mg/kg bw	24671.05 mg/kg Not classified	Yes	None
LD_{50} dermal, rat (OECD 402)	> 5000 mg/kg bw	>2000 mg/kg Not classified	Yes	None
LC_{50} inhalation, rat (OECD 403)	6.1 mg/L air	>5mg/L Not classified	Yes	None
Skin irritation, rabbit (OECD 404)	Non-irritant	Not irritant Not classified	Yes	None
Eye irritation, rabbit (OECD 405)	Mild irritant.	Eye irritant Category 2	Yes	None
Skin sensitisation, mouse (OECD 429, LLNA)	Non-sensitising	Not a skin sensitizer Not classfied	Yes	None
Supplementary studies for combinations of	No data – not			

plant protection products	required			

[1] Proposed acute toxicity classifications are based on A20607B study results.

Fludioxanil, metalaxyl-M and sedaxane

The following data on metabolite CSCD465008 with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were submitted. Note that the relevance assessment of the metabolites CSCD465008 are reported in Part B 10.

There are not relevant metabolites for fludioxonil. The PEC_{GW} for metabolites of metalaxyl-M (NOA409045, CGA67868 and SYN546520) are all below 0.1 µg/L. The PEC_{GW} for the metabolites of sedaxane (CSAA798670 and CSCD728931) are all below 0.1 µg/L. Therefore, relevance assessment is not required.

3.5.2 Operator exposure

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	Estimates using the [redacted] (2006) study predict that the proposed uses of 'Vibrance SB' as an undiluted seed treatment on sugar and fodder beet seeds will result in a level of systemic exposure to metalaxyl-M equal to 0.000457 mg/kg bw/day (equivalent to 0.57% 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 'Vibrance SB' will result in a level of exposure to metalaxyl-M equal to 0.0008 mg/kg bw/day (equivalent to 1% 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 'Vibrance SB' with regards to human health, the following operator protection phrases are required for the operators being directly involved in the seed treatment process: <u>Seed treatment product label:</u> • 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)*, suitable protective gloves and face protection (faceshield) when cleaning machinery. *With liquid tight connections for the whole body to at least EN 14605 Type 3 or equivalent.

A20607B is to be applied to sugar beet at a rate of 33.3 mL/seed unit. A seed unit is 100,000 seeds. It is expected that up to 1500 units of sugar beet will be treated per day.

<u>Industrial seed treatment</u>

Operator exposure for use of A20607B was modelled using the "SeedTROPEX sugar beet treatment study data" (75th percentile) for industrial seed treatment in risk assessment for plant protection product [[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. Unpublished. The data are

property of the SeedTROPEX Group].

The outcome of the estimations 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 for these active substances

According to the exposure calculations, it can be concluded that the risk for the operator using A20607B on sugar beet seeds (critical use: Industrial Seed treatment of sugar beet seeds, max. 99.9 L product/day) is acceptable with the use of gloves, coverall, half-face mask and safety spectacles during mixing/loading, calibration and cleaning, except bagging.

Mobile treaters and On-farm treatment

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

Since there are no representative data available in calculation models, a field study measuring the operator exposure has been provided. Please, refer to the Appendix 4 of the Part B Section 6 for further detail.

3.5.3 Worker exposure

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	Estimates using the [redacted] (2008) study predict a level of systemic exposure equivalent to 0.25% of the AOEL of metalaxyl-M for a worker loading/sowing treated seed without protection from clothing or PPE. This is within acceptable limits. The following phrase should be included on the seed bag label: Treated seed bag label: • Operators must wear suitable protective gloves when handling treated seed and contaminated seed sowing equipment.

Worker exposure for A20607B was modelled using "the SeedTROPEX Maize sowing study data" (75th percentile) during the loading and sowing of sugar beet seeds [[redacted] (2007) Determination of operator exposure to imidacloprid during loading/sowing of GAUCHO® treated maize seeds under realistic field conditions in Ger-many and Italy. Amendment No 1 to Final Report. SGS Institut Fresenius, Im Maisel 14, D-65232 Taunusstein. Study No. IF-05/00328969; 25 October 2007. Un-published. The data are property of the SeedTROPEX Group].

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.

According to the exposure calculations, it can be concluded that the risk for the worker A20607B on sugar beet seeds (critical use: Loading and sowing treated large seeds, 33.3 mL/seed unit) is acceptable with the use of gloves while loading hopper.

Measurement of worker exposure

Since there are no representative data in available calculation models, a field study measuring the worker exposure has been provided. A summary of the study is presented in Appendix 4, Part B Section 6.

3.5.4 Bystander and resident exposure

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	The treatment of sugar and fodder beet 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 'Vibrance SB' during the seed treatment process. Therefore, no resident/bystander exposure risk is expected. No further assessment is necessary.

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.

Combined Exposure and Risk Assessment

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	HSE notes that under the Article 7 evaluation of metalaxyl-M, the product 'Vibrance SB' (A20607B) 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 'Vibrance SB' has not been considered.

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 A20607B is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is

required.

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

3.6.1 Residues

<table>
<tr><th colspan="2">EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY</th></tr>
<tr><td>Name of authority</td><td>HSE Chemicals Regulation Division (CRD), UK</td></tr>
<tr><td>Reviewer's comments</td><td>
<u>Metalaxyl-M only:</u>

Acceptable plant and animal metabolism data, as well as feeding study data were submitted in the EU RAR for metalaxyl-M.

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.

Sufficient processing data is available in the EU RAR for metalaxyl-M.

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.

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 sedaxane or fludioxonil.

<u>Maximum residue levels (MRLs) - Metalaxyl-M only</u>

GB MRLs
<u>GB MRLs in force</u>

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

Active: metalaxyl-MError! 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
<table>
<tr><th>Code</th><th>Commodity to which MRL applies</th><th>MRL required for proposed use (mg/kg)</th><th>GB MRL in force (as outlined in the GB MRL Statutory Register GB MRL decision no. 2022/013) (mg/kg)</th><th>Potential future GB MRL (mg/kg)ǂ</th></tr>
<tr><td>0900010</td><td>Sugar beet roots</td><td>0.01*</td><td>0.01*</td><td>-</td></tr>
</table>
ǂ Agreed future MRLs outlined in the Register or proposed MRLs outlined in the Published MRL reviews List

<u>Conclusion on GB MRLs</u>
</td></tr>
</table>

	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 metalxyl and metalaxyl-M. No GB MRL data gaps relevant to the MRLs considered in this assessment were identified in the MRL review. **Conclusion** Authorisation for the proposed uses of 'Vibrance SB' on sugar beet at the proposed GAP can be recommended; with respect to metalaxyl-M.

Fludioxonil

A20607B is used as a seed treatment on sugar beet in the UK.

Sugar beet is a major crop in both northern and southern Europe therefore generally require 8 trials in each region. **SANCO 7525/VI/95 rev. 10.3** states that in situations where residues are below the limit of quantification only 4 residue trials are required. Therefore, sufficient trials are available to support the proposed use. The trials can be extrapolated to fodder beet.
The intended GAP is one application at 0.97 g a.s./ha (equiv. to 7.49 µg a.s./seed; 31.22 g a.s./100 kg seed).
Residue trials were conducted with sugarbeet seeds treated with 11 and 7.3 µg a.s./seed and drilled at between 99,207 to 120,000 seeds per hectare (equiv. to 0.72 to 1.1 g a.s./ha). Sugarbeet were sampled at normal commercial harvest and the roots and tops analysed separately. All residues were less than the limit of quantification (LoQ) of the method (0.02 and 0.01 mg/kg).
The trials demonstrate that residues of fludioxonil in sugar beet following seed treatment are not expected. This is confirmed by the metabolism studies previously reviewed for cereals (see Section 7.2.2) where application to seed of up to 7.30g fludioxonil per 100kg of seed show residues in the edible part of the crop are unlikely.
The data submitted show that no exceedance of current EU MRLs for fludioxonil will occur.
Products from sugarbeet could potentially form a part of livestock diets in the EU. Residues of fludioxonil in all plant parts were less than the LOQ in all trials.
The use of A20607B on sugarbeet is considered acceptable.

Metalaxyl-M

A20607B is used as a seed treatment on sugar beet in the UK.

Sugar beet is a major crop in northern and southern Europe (**SANCO 7525/VI/95 rev.10.3**); and therefore generally requires eight trials in the residue region. This guidance also states that in situations where residues are below the limit of quantification only 4 residue trials are required. Therefore, sufficient trials are available to support the proposed use. The sugar beet trials can be extrapolated to fodder beet.
The intended GAP is one application at 0.62 g a.i./ha (equiv. to 19.98 g a.s./100kg seed or 4.8 µg as/ seed.
Five trials on sugar beet were conducted in southern Europe at an overdosed application rate of 65.9 g a.i/100 kg seed. In these sugar beet trials residues in the roots were all at <0.01 mg/kg. In northern Europe, five trials were conducted at an overdose application rate range of 62.2 – 65.9 g a.i/100 kg seed. In these sugar beet trials residues in the roots were all at <0.01 mg/kg. All sugar beet residues are within the current MRL.

The trials demonstrate that residues of metalaxyl-M in sugar beet following seed treatment are not expected. This is confirmed by the metabolism studies previously reviewed for cereals (see Section 7.3.2) where application to seed of up to 157g of metalaxyl-M per 100kg of seed show residues in the edible part of the crop are unlikely.
Therefore, sufficient trials are available to support the proposed uses of A20607B and to conduct a risk assessment. The sugar beet can be extrapolated to support fodder beet.
The data submitted show that no exceedance of the MRL will occur. The use of A20607B on sugar beet and fodder beet is acceptable.

Sedaxane

Sugar beet is a major crop in northern and southern Europe (**SANCO 7525/VI/95 rev.10.3**); sufficient trials are available to support the proposed use.
The intended use is one application at 0.65 g a.s./ha (5.00 µg a.s./seed; 20.81 g a.s./100 kg seed).
Four new trials each in northern and southern Europe were conducted to support the critical Syngenta use on sugar beet. In each trial seeds were treated at a rate of 5.71-5.98 µg a.s./seed (0.571-0.598 g a.s./ha). In these trials residues of sedaxane in sugar beet roots and tops were below the LOQ (<0.01 mg/kg).

The data submitted show that no exceedance of the MRL will occur. The intended uses of A20607B are considered acceptable.

3.6.2 Consumer exposure

Fludioxonil

The output report from the chronic risk assessment is presented in Part B Section 7 Appendix 3.
The use of fludioxonil in A20607B does not represent unacceptable chronic risks for the consumer. An acute assessment is not required.
The output reports from the chronic and acute risk assessments are presented in Part B Section 7 Appendix 3.

Table 3.6-1: Consumer risk assessment

NEDI (% ADI)	36 % (based on UK Toddler)
NESTI (% ARfD)	Not applicable (no ARfD)
TMDI (% ADI) according to EFSA PRIMo3.1	63 % (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 PRIMo3.1	Not applicable (no ARfD set for fludioxonil)

The proposed uses of fludioxonil in A20607B do not represent unacceptable chronic risks for the consumer.

Metalaxyl-M

The output reports from the chronic and acute risk assessments are presented in Part B Section 7 Appendix 3.

Table 3.6-2: Consumer risk assessment

NEDI (% ADI)	9 % (based on UK Toddler)
NESTI (% ARfD)	Other types of offal: 0.4 % (based on infant)
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: 0.4% Milk cattle: 0.2% Bovine kidney: 0.2% Swine edible offals: 0.1% Bovine liver: 0.08% Swine kidney: 0.05% Milk: Goat: 0.05% Poultry: Muscle/meat: 0.03 % Eggs: Chicken: 0.02 % Swine: Muscle/meat: 0.02 % Bovine: Muscle/meat: 0.01 % Other farmed animals: Muscle/meat: 0.01 % Swine: Liver: 0.01 % Equine: Muscle/meat: 0.01 % Poultry: Liver: 0.01 %
IESTI Processed (% ARfD) according to EFSA PRIMo 3.1	Sugar beets (root) / sugar: 0.2% (based on NL child)

The proposed uses of Metalaxyl-M in A20607B do not represent unacceptable acute and chronic risks for the consumer.

Sedaxane

Extensive calculation sheets are presented in Part B Section 7 Appendix 3.

Table 3.6-3: Consumer risk assessment

NEDI (% ADI)	1 % (based on UK Toddler)
NESTI (% ARfD)	Milk: 0.4 % (based on infant)
TMDI (% ADI) according to EFSA PRIMo 3.1	0.8% (NL toddler)
IEDI (% ADI) according to EFSA PRIMo 3.1	Not Necessary
IESTI RAC (% ARfD) according to EFSA PRIMo 3.1	0.4% (Milk: Cattle)
IESTI Processed (% ARfD) according to EFSA PRIMo 3.1	0.4% (Sugar beets (root) / sugar)

The proposed uses of sedaxane in A20607B 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 A20607B containing fludioxonil, metalaxyl-M and sedaxane 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 contribtions 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 46% of the ADI.

Contribution from Fludioxonil is 36%
Contribution from Metalaxyl-M is 9%
Contribution from Sedaxane is 1%

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 fludioxonil, metalaxyl-M and sedaxane.

Therefore, the proposed uses of A20706B in the UK do not present an unacceptable chronic risk to the consumer.

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 0.7% of the ARfD.

Milk (0.7% - UK infant)
Contribution from Metalaxyl-M is 0.2%
Contribution from Sedaxane is 0.4%
Other types of offal (0.5% - UK infant)
Contribution from Metalaxyl-M is 0.4%
Contribution from Sedaxane is 0%
Sugar Beet (0.4% - UK toddler)
Contribution from Metalaxyl-M is 0.2%
Contribution from Sedaxane is 0.3%

All types of kidney (0.2% - UK toddler)
Contribution from Metalaxyl-M is 0.2%
Contribution from Sedaxane is 0%
All types of liver (0.1% - UK infant)
Contribution from Metalaxyl-M is 0.1%
Contribution from Sedaxane is 0%

Therefore, the uses of A20607B 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)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	**Summary of PEC values** **Table HSE-03** Final PEC values for use in risk assessments for the product 'Vibrance SB'.

Substance	PEC value	Notes
PECsoil (mg/kg)		
Metalaxyl-M	0.001	
Formulation	0.060	
PECgw (µg/L)		
Metalaxyl-M	<0.001	All scenarios and models
NOA409045	0.020	PEARL, Hamburg
CGA67868	<0.001	All scenarios and models
SYN546520	0.093	PEARL, Hamburg
PECsw (µg/L) – note all values calculated only from drainage; spray drift not a relevant route of exposure due to use as seed treatment		
Metalaxyl-M	0.091	
PECsed (µg/kg) – note all values calculated only from drainage; spray drift not a relevant route of exposure due to use as seed treatment		
Metalaxyl-M	0.085	

Fludioxonil

Studies on the aerobic and anaerobic degradation rates of fludioxonil 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 use. Additional information on this study is detailed in Part B8, 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 the EU review of fludioxonil (***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. All rele-

vant detailed experimental information has been submitted for the 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 Scientific Report* 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. Additional data were not required as a result of the EU review.

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. All relevant detailed experimental information has been submitted for the EU review of metalaxyl-M (***Metalaxyl-M, EFSA Journal 2015; 13(3):3999***).

Sedaxane

Studies on the aerobic and anaerobic degradation rates of sedaxane and its metabolites CSAA798670 and CSCD465008 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 sedaxane ***(Sedaxane, EFSA Journal 2013;11(1):3057)***. Additional information on the aerobic soil degradation of metabolite CSCD728931 is detailed in Part B8.

Studies on the field dissipation rate of sedaxane and its metabolite CSCD465008 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 sedaxane (***Sedaxane, EFSA Journal 2013;11(1):3057***).

Studies on the mobility of sedaxane and its metabolites CSAA798670 and CSCD465008 in soil are considered to be data provided in support of the active substance. Additional data were not required as a result of the EU review, however to refine risk assessment endpoints, further metabolite data have been generated for metabolite CSCD728931. These additional data have been provided in Part B8.

Since reliable adsorption coefficient values were obtained from the adsorption/desorption studies reported for sedaxane and its metabolites, column leaching studies were not conducted Based on the properties of sedaxane and the results of the soil and groundwater modelling, lysimeter and field leaching studies are not required

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

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. There-

fore, for seed treatment use, these metabolites are not considered in PEC_S assessments.

PECs for fludioxonil

The PECs of fludioxonil has been assessed in accordance with FOCUS guidelines following a tiered approach using FOCUS groundwater crop interception values and the worst case laboratory DT_{50} value reported in the ***Fludioxonil EFSA Scientific Report (2007) 110, 1-85*** (Tier I) and the maximum DT_{50} derived from field dissipation trials (Tier II) using CRD PEC_{SOIL} Excel spreadsheet.

Based on the recommended use rate at 0.97 g a.s./ha, the maximum initial PEC_S value of fludioxonil after application to soil as seed treatment was 0.001 mg/kg (5 cm soil depth, Tier I & Tier II). Plateau concentration and $PEC_{accumulation}$ values considering 20 cm tillage depth were <0.001 mg/kg and 0.002 mg/kg, respectively at Tier 1 and <0.001 mg/kg and 0.001 mg/kg, respectively at Tier 2.

Metalaxyl-M

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

PECs for metalaxyl-M and its metabolite NOA409045

The PEC_S of metalaxyl-M and its metabolite NOA409045 have been assessed in accordance with FOCUS guidelines using FOCUS groundwater crop interception values and the worst case DT_{50} value from field trials 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 at 0.62 g a.s./ha, the maximum initial PEC_S value of metalaxyl-M and its metabolite NOA409045 after application to soil as a seed treatment were 0.001 mg/kg and 0.001 mg/kg respectively (5 cm soil depth). The field DT_{90} of metalaxyl-M and its metabolite NOA409045 are <365d, and thus calculations estimating the potential accumulation of metalaxyl-M and its metabolite NOA409045 in soil were not performed.

Sedaxane

Predicted Environmental Concentrations of sedaxane and its metabolites CSAA798670 and CSCD465008 in soil (PEC_S) listed below are detailed in Part B Section 8 of this submission.

PECs for sedaxane and its metabolites CSAA798670 and CSCD465008

The PECs in soil of sedaxane and its metabolites CSAA798670 and CSCD465008 have been assessed in accordance with FOCUS guidelines using FOCUS groundwater crop interception values and the non-normalised worst case field DT_{50} value of 438 days for sedaxane, maximum laboratory DT_{50} for the metabolite CSAA798670 and CSCD465008 (***LoEP, EFSA, 2013***) as well as maximum field DT_{50} for CSCD465008 (***EFSA Journal 2012, 10(1):2522***) using CRD PEC_{SOIL} Excel spreadsheet.

Based on the recommended use rate at 0.65 g a.s./ha, the maximum initial PEC_S value of sedaxane and its metabolites CSAA798670 and CSCD465008 after application to soil as a seed treatment were 0.001 mg/kg for sedaxane and < 0.001 mg/kg for the metabolites (CSAA798670 and CSCD465008). Plateau concentration and $PEC_{accumulation}$ values considering 20 cm tillage depth were <0.001 mg/kg and 0.001 mg/kg respectively for sedaxane and < 0.001 mg/kg (Plateau concentration and $PEC_{accumulation}$) for metabolite CSCD465008. The field DT_{50} of metabolite CSAA798670 is <100d, and thus calculations estimating the potential accumulation of CSAA798670 in soil was not performed.

PEC_S of A20607B on sugar beet

Based on the recommended use rate of 44.7 g A20607B/ha, the maximum initial PEC_S value of the formulation A20607B after application to soil as seed treatment was 0.0596 mg/kg (5 cm soil depth).

The results for PEC_S calculations are used in the Ecotox risk assessment, as detailed in Part B9 of this submission.

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

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 UK core assessment, Appendix 3.

The PEC of fludioxonil in ground water (PEC_{GW}) has been assessed with the FOCUS scenarios considered relevant for the UK (Châteaudun, Hamburg, Kremsmünster and Okehampton) to obtain outputs from the FOCUS PEARL (v4.4.4), FOCUS PELMO (v5.5.3) and MACRO v5.5.4 models and the endpoints established in the EU review of fludioxonil (***Fludioxonil EFSA Scientific Report (2007) 110, 1-85)***. Since the present use is a seed treatment, exposure to light and thus formation of the metabolites is not relevant.

Based on the recommended use rate at 0.97 g a.s./ha, the overall maximum PEC_{GW} at 1 m depth for fludioxonil following 20 years of use on sugar beet was below 0.001 µg/L in all models, all scenarios.

Based on the assessment, the use of fludioxonil is not expected to lead to leaching into ground water 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 have not been previously reviewed at EU level and is provided in support of this assessment in Part B Section 8 UK core assessment, Appendix 3.
The PEC of metalaxyl-M and metabolites (NOA409045, CGA67868 and SYN546520) in ground water (PEC_{GW}) has been assessed with the FOCUS scenarios considered relevant for the UK (Châteaudun, Hamburg, Kremsmünster and Okehampton) to obtain outputs from the FOCUS PEARL (v4.4.4), FOCUS PELMO (v5.5.3) and MACRO v5.5.4 models and the endpoints established in the EU list of endpoints of metalaxyl-M (***Metalaxyl-M; EFSA Journal 2015; 13(3):3999***). Different values of formation fraction (FF) from metalaxyl-M metabolite NOA409045 to SYN546520 were simulated separately in modelling and were presented as tier 1 and tier 2. For tier 1, the FF of SYN546520 = 0.47, as described in EFSA (2015) was used. Additionally, for tier 2, a proposed FF of SYN546520 = 0.1 (derived from inverse modelling) was presented.

The maximum PEC_{GW} of metalaxyl-M at 1m depth following 20 years use applied as seed treatment on sugar beet at 0.62 g a.s./ha, was <0.001 µg/L (all models/all scenarios). The potential for the metabolites NOA409045, CGA67868 and SYN546520 to leach to ground water has been assessed using the same approach.

The PEC_{GW} of CGA67868, NOA409045 and SYN546520 were less than 0.1 µ/L in all models, all scenarios.

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.

Sedaxane

Groundwater modelling on sedaxane and its metabolites CSAA798670, CSCD465008 and CSCD728931 have not been previously reviewed at EU level and is provided in support of this assessment in Part B Section 8 UK core assessment, Appendix 3.

The PEC of sedaxane, CSAA798670, CSCD465008 and CSCD728931 in ground water (PEC_{GW}) has been assessed with the FOCUS scenarios considered relevant for the UK (Châteaudun, Hamburg, Kremsmünster and Okehampton) to obtain outputs from the FOCUS PEARL (v4.4.4), FOCUS PELMO (v5.5.3) and MACRO v5.5.4 models and the endpoints established in the EU review of sedaxane ***(Sedaxane EFSA Journal 2013;11(1):3057)*** unless otherwise detailed in Part B8. For example, additional endpoints for metabolite CSCD465008 established in the EU approval of fluxapyroxad **(*Fluxapyroxad EFSA Journal 2012; 10(1):2522***) were used, whilst for metabolite CSCD728931 further metabolite data have been generated following a data gap noted in the EU review.

The maximum PEC_{GW} of sedaxane at 1m depth following 20 years use applied as seed treatment on sugar beet at 0.65 g a.s./ha, was <0.001 µg/L (all models/all scenarios). The potential for the metabolites CSAA798670, CSCD465008, and CSCD728931 to leach to ground water has been assessed using the same approach.

The PEC_{GW} of CSAA798670, and CSCD728931 were less than 0.1 µg/L in all models/all scenarios. The maximum 80th percentile PEC_{GW} value of metabolite CSCD465008 (Tier 1) was below 0.75 µg/L (maximum PEC_{GW} 0.129 µg/L) and declined to <0.1 µg/L in the Tier 2 assessment (PEC_{GW} 0.036 µg/L). An assessment concluding the non-relevance of CSCD465008 in groundwater is presented in the Part B10 UK core assessment.

Based on the assessment, the use of sedaxane is not expected to lead to leaching into ground water 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})

Fludioxonil

The PEC_{SW} and PEC_{SED} of fludioxonil and its metabolite CGA192155 following entry *via* drainage have been assessed according to standard Tier I calculations recommended in the national requirements in the UK. Since the present use is a seed treatment, spray drift can be excluded a s a potential entry path to surface water. For the Tier I drainage assessment, applications were assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case.

Based on the recommended use rate at 0.97 g a.s./ha on sugar beet, the PEC_{SW} and PEC_{SED} values of fludioxonil arising from drainage were 0.001 µg/L and 0.002 µg/kg, respectively.

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

The results for PEC_{SW} and PEC_{SED} for the active substance and its metabolite were used for the ecotoxicological risk assessment.

Metalaxyl-M

The PEC_{SW} and PEC_{SED} of metalaxyl-M and its metabolites following entry *via* drainage have been assessed according to standard Tier I calculations recommended in the national requirements in the UK. 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 assessment, applications were assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case.

Based on the recommended use rate at 0.62 g/a.s./ha on sugar beet, the PEC_{SW} and PEC_{SED} values of metalaxyl-M arising from drainage were 0.033 µg/L and 0.031 µg/kg, respectively.

The Predicted Environmental Concentration of the metabolite NOA409045 in surface water and sediment (PEC_{SW} and PEC_{SED}) has been assessed using the same approach. The maximum PEC_{SW} and PEC_{SED} values of metabolite NOA409045 were 0.061 µg/L and 0.065 µg/kg, respectively.

PEC_{SW} and PEC_{SED} values for the active substance and its metabolites were used for the ecotoxicological risk assessment.

Sedaxane

The PEC_{SW} and PEC_{SED} of sedaxane and its metabolites following entry *via* drainage have been assessed according to standard Tier I calculations recommended in the national requirements in the UK. 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 assessment, applications were assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case.

Based on the recommended use rate of sedaxane at 0.65 g a.s./ha on sugar beet, the maximum PEC_{SW} and PEC_{SED} values of sedaxane arising from drainage were 0.025 µg/L and 0.102 µg/kg, respectively.
The Predicted Environmental Concentration of the metabolite CSAA798670, CSCD465008, CSCD668094 and CSCD668095 in surface water and sediment (PEC_{SW} and PEC_{SED}) have been assessed using the same approach.

The maximum PEC_{SW} value of metabolite CSAA798670 due to drainage was 0.007 µg/L.

The maximum PEC_{SW} value of metabolite CSCD465008 due to drainage was 0.015 µg/L.

The maximum PEC_{SW} value of metabolite CSCD668094 due to drainage was 0.004 µg/L.

The maximum PEC_{SW} value of metabolite CSCD668095 due to drainage was 0.004 µg/L.

The results for PEC_{SW} and PEC_{SED} for the active substance and its metabolites were used for the ecotoxicological risk assessment.

PEC_{SW} of A20607B on sugar beet

As formulations consist of a mixture of components, the entry routes drainage and runoff cannot be estimated by the FOCUS models. Usually, only spray drift is assessed for the formulation. However, since spray drift is not a relevant entry path for seed treatments, the PEC_{SW} for the formulation was not assessed.

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

Fludioxonil

The fate and behaviour in air of fludioxonil were evaluated during the 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 A20607B 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 were evaluated during the 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 compared to other routes (spray drift and drainage). Moreover, A20607B is a seed treatment and the seeds are buried into soil which reduces volatilisation. Thus, PEC air is deemed not required for metalaxyl-M.

Sedaxane

The fate and behaviour in air of sedaxane were evaluated during the EU review ***(Sedaxane EFSA Journal 2013;11(1):3057)***. No additional studies have been performed.

The low vapour pressure for sedaxane (6.5 x 10^{-8} Pa at 20°C) indicates a low potential for volatilisation from soil under practical conditions of use as application is made as a seed treatment. Environmental concentrations of sedaxane in the air following application will be short lived. The calculation half-life for the reaction of the active substance in the gas phase in the troposphere was made using the Atkinson calculation and found to be 5.1 hours. The predicted concentration in air (PEC_{AIR}) will be negligible.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

The acute and long-term risks of A20607B to birds and mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with sedaxane, fludioxonil and metalaxyl-M, and maximum residues occurring on food items following applications according to the proposed use pattern.

Risk of secondary poisoning has also been assessed, as sedaxane and fludioxonil both have log Pow >3.0. The risk to birds and mammals from exposure via drinking water has also been assessed.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, indicating that the risk to birds and mammals is acceptable following use of A20607B according to the proposed use pattern. Additionally, the acute TER values for the mixture exceed the relevant triggers, indicating an acceptable risk to birds and mammals from the use of A20607B.

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, using worst-case PEC_{SW} values for sedaxane, fludioxonil, metalaxyl-M and their respective metabolites are less than the trigger value of 1, indicating that the risk to aquatic organisms is acceptable following use of A20607B according to the proposed use pattern.

The RQ_{mix} values for the sedaxane/fludioxonil/metalaxyl-M mixture, using worst-case RAC and PECsw values are less than the trigger value of 1, indicating that the combined risk to aquatic organisms is acceptable following use of A20607B according to the proposed use pattern.

3.8.3 Effects on bees

The risk of A20607B 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 sedaxane, fludioxonil and metalaxyl-M are less than the relevant triggers, indicating that the risk to honeybees is acceptable following use of A20607B, according to the proposed use pattern.

The EPPO scheme suggests that effects on growth or development can be excluded when considering sedaxane, fludioxonil and metalaxyl-M are not an IGR. To further demonstrate the low risk, the chronic larval risk of A20607B to honeybees was assessed from ETRs following EPPO 2010 scheme. Risk was estimated from larval studies with sedaxane (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 A20607B, according to the proposed use pattern.

3.8.4 Effects on other arthropod species other than bees

As A20607B is a seed treatment, it is not appropriate to conduct a standard tiered risk assessment. The risk assessment is therefore undertaken using the endpoint generated with *Aleochara bilineata* compared to the maximum in-field soil PEC value.

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

The in-field HQ value was below the trigger value of 2 for the worst-case use scenario (44.7 g A20607B/ha in sugar and fodder beet) indicating that the risk to in-field non-target arthropods is acceptable following the use of A20607B according to the proposed use pattern.

3.8.5 Effects on soil organisms

Soil meso- and macrofauna

The long-term risk of A20607B to earthworms was assessed from long-term toxicity exposure ratios (TERs) between the selected toxicity endpoints for sedaxane, fludioxonil, metalaxyl-M, their respective relevant metabolites, A20607B and the corresponding maximum PECsoil for each entity. The chronic TER values are greater than the Regulation (EU) 546/2011 trigger of 5, indicating that the risk to earthworms is acceptable following use of A20607B according to the proposed use pattern.

The risk of A20607B to other non-target soil macro-organisms, as represented by Collembola and *Hypoaspis*, was assessed from long-term toxicity exposure ratios (TERs) between the selected toxicity endpoints for sedaxane, fludioxonil, metalaxyl-M, their respective relevant metabolites, A20607B and the corresponding maximum PECsoil for each entity. The chronic TER values are greater than the Regulation (EU) 546/2011 trigger of 5, indicating that the risk to Collembola and *Hypoaspis* is acceptable following use of A20607B according to the proposed use pattern.

Soil microbial activity

The risk of sedaxane, fludioxonil, metalaxyl-M and their respective metabolites, as well as A20607B to soil micro-organisms was evaluated by comparison of the maximum concentrations with effects <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 A20607B according to the proposed use pattern.

3.8.6 Effects on non-target terrestrial plants

The formulation A20607B is a fungicide seed treatment and as such studies of the effects on non-target terrestrial plants is not required. Since A20607B is a seed treatment there will be negligible exposure of or risk to non-target terrestrial plants in the off-field environment.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No other groups of terrestrial non-target organisms are considered to be at risk from the intended use of A20607B as a treatment applied to sugar and fodder beet seeds.

3.9 Relevance of metabolites (Part B, Section 10)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	The 80th percentile PECgw values for the proposed uses have been calculated with the FOCUS PEARL, PELMO and MACRO models. Parent and metabolite PECgw values were below the 0.1 µg/L trigger value in all scenarios. No further consideration is required.

Fludioxonil

There are no relevant metabolites for fludioxonil.

Metalaxyl-M

The metalaxyl-M metabolites NOA409045, SYN546520 and CGA67868 are predicted to occur in groundwater at concentrations below 0.1 µg/L (see A20607B Part B Section 8 UK core assessment). 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.

Sedaxane

The sedaxane metabolites CSAA798670 and CSCD728931 are predicted to occur in groundwater at concentrations below 0.1 µg/L (see A20607B Part B Section 8 UK core assessment). 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.

The sedaxane metabolite CSCD465008 is predicted to occur in groundwater at concentrations above 0.1 µg/L in Tier 1 assessment (see A20607B Part B Section 8 UK core assessment). Concentrations declined to <0.1 µg/L in the Tier 2 assessment. 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.

CSCD465008

The relevance of the sedaxane groundwater metabolite CSCD465008 has already been assessed and the assessment agreed at EU level (see **Sedaxane – Final addendum to the Draft Assessment Report (DAR), June 2012**).

CSCD465008 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 CSCD465008

	Assessment step	**Result of assessment**	
	STEP 1	Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2	Max PEC_{GW}	0.129 µg/L, Tier 1
		Based on	Modelling result using FOCUS PEARL v4.4.4 / Sugar beet 0.65 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 :	• Oral LD50 >2000 mg/kg • 28-day dietary, rat: NOAEL ≥1000 mg/kg/day • 90-day dietary, rat: NOAEL ≥958.4/928.7mg/kg/day in M/F • Developmental toxicity, rabbit: Maternal NOAEL = 300 mg/kg/day LOAEL = 1000 mg/kg/day based on increased mortality and abortions. Fetal NOAEL >1000 mg/kg/day
			Classification of parent	Not classified
			Classification of metabolite	Not classified
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

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

A20607B contains fludioxonil which is approved as a candidate for substitution because it meets two of PBT criteria. A derogation under Art 50 until end of 2022 applies for this product.

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	Not applicable.

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	Not applicable.

Appendix 3 Letter of Access

Not applicable.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP Section 2	[redacted]	26/06/2017	A20607B - Chemical Characterization of Batch SMU7AL007 Report No. CHMU170254 Document No. VV-858601 Test Facility GLP Testing Facility WMU, Syngenta Crop Protection GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP Section 2	[redacted]	23/04/2015	A20607B - Chemical Characterization Before Storage of Batch SMU4DP001 Report No. SMG12799 Document No. VV-412226 , A20607B_10178 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2 & KIIIA1 2.6.1
KCP 2.1	[redacted]	12/05/2015	A20607B - Physical and Technical Properties of Batch SMU4DP001 Report No. SMG12801 Document No. VV-412228 , A20607B_10183 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.1 & KIIIA1 2.4.2 & KIIIA1 2.8.2 & KIIIA1 2.8.3.1 & KIIIA1 2.8.5.2 & KIIIA1 2.8.8.2 & KIIIA1

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
								2.10.1
KCP 2.2	[redacted]	15/08/2017	A20607B - Safety Study Report No. HT17/560 Document No. VV-467979 , A20607B_10253 Test Facility Syngenta Technology & Engineering GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.3	[redacted]	15/08/2017	A20607B - Safety Study Report No. HT17/560 Document No. VV-467979 , A20607B_10253 Test Facility Syngenta Technology & Engineering GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 2.3	[redacted]	02/10/2014	A20607B - Safety Study Report No. HT14/537 Document No. VV-412230 , A20607B_10186 Test Facility Syngenta Huddersfield Manufacturing Centre GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.2.1 & KIIIA1 2.2.2 & KIIIA1 2.3.1 & KIIIA1 2.3.2 & KIIIA1 2.3.3
KCP 2.4	[redacted]	12/05/2015	A20607B - Physico-Chemical Characteristics of Batch SMU4DP001 Report No. SMG12800 Document No. VV-412229 , A20607B_10185 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.4.1 & KIIIA1 2.5.2 & KIIIA1 2.5.3 & KIIIA1 2.7.4 & KIIIA1 2.8.3.1 & KIIIA1

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
								2.8.6.1 & KIIIA1 2.10.2
KCP 2.4	[redacted]	12/05/2015	A20607B - Physical and Technical Properties of Batch SMU4DP001 Report No. SMG12801 Document No. VV-412228 , A20607B_10183 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.1 & KIIIA1 2.4.2 & KIIIA1 2.8.2 & KIIIA1 2.8.3.1 & KIIIA1 2.8.5.2 & KIIIA1 2.8.8.2 & KIIIA1 2.10.1
KCP 2.5	[redacted]	12/05/2015	A20607B - Physico-Chemical Characteristics of Batch SMU4DP001 Report No. SMG12800 Document No. VV-412229 , A20607B_10185 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.4.1 & KIIIA1 2.5.2 & KIIIA1 2.5.3 & KIIIA1 2.7.4 & KIIIA1 2.8.3.1 & KIIIA1 2.8.6.1 & KIIIA1 2.10.2
KCP 2.6	[redacted]	23/04/2015	A20607B - Chemical Characterization Before Storage of Batch SMU4DP001	N	Y	Data protection started with MAPP 18588 on 19.06.2018;	SYN	Y

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Report No. SMG12799 Document No. VV-412226 , A20607B_10178 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished			Expiry date 19.06.2028		KIIIA1 2 & KIIIA1 2.6.1
KCP 2.7	[redacted]	12/05/2015	A20607B - Physico-Chemical Characteristics of Batch SMU4DP001 Report No. SMG12800 Document No. VV-412229 , A20607B_10185 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.4.1 & KIIIA1 2.5.2 & KIIIA1 2.5.3 & KIIIA1 2.7.4 & KIIIA1 2.8.3.1 & KIIIA1 2.8.6.1 & KIIIA1 2.10.2
KCP 2.7	[redacted]	15/07/2019	A20607B - Storage Stability and Shelf Life Statement (3 years 20 °C) in Packaging Made of HDPE Report No. 300144808 Document No. VV-472257 , A20607B_10346 Test Facility Syngenta Biosciences Pvt. Ltd. Not GLP Unpublished	N	N	-	SYN	N
KCP 2.7	[redacted]	21/05/2015	A20607B - Storage Stability and Shelf Life Statement (2 Weeks 54 °C) in Packaging Made of HDPE according to CIPAC MT 46.3 Report No. 300040092 Document No. VV-412223 , A20607B_10176 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIIIA1 2.7.1 & KIIIA1 4.1.3
KCP	[redacted]	12/05/2015	A20607B - Physical and Technical Properties of Batch	N	Y	Data protection started with	SYN	Y

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
2.8.2			SMU4DP001 Report No. SMG12801 Document No. VV-412228 , A20607B_10183 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished			MAPP 18588 on 19.06.2018; Expiry date 19.06.2028		KIIIA1 2.1 & KIIIA1 2.4.2 & KIIIA1 2.8.2 & KIIIA1 2.8.3.1 & KIIIA1 2.8.5.2 & KIIIA1 2.8.8.2 & KIIIA1 2.10.1
KCP 2.8.3	[redacted]	12/05/2015	A20607B - Physical and Technical Properties of Batch SMU4DP001 Report No. SMG12801 Document No. VV-412228 , A20607B_10183 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.1 & KIIIA1 2.4.2 & KIIIA1 2.8.2 & KIIIA1 2.8.3.1 & KIIIA1 2.8.5.2 & KIIIA1 2.8.8.2 & KIIIA1 2.10.1
KCP 2.8.3	[redacted]	12/05/2015	A20607B - Physico-Chemical Characteristics of Batch SMU4DP001 Report No. SMG12800 Document No. VV-412229 , A20607B_10185 Test Facility Syngenta Biosciences Pvt. Ltd. GLP	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.4.1 & KIIIA1 2.5.2 &

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Unpublished					KIIIA1 2.5.3 & KIIIA1 2.7.4 & KIIIA1 2.8.3.1 & KIIIA1 2.8.6.1 & KIIIA1 2.10.2
KCP 2.8.5.1	[redacted]	12/05/2015	A20607B - Physico-Chemical Characteristics of Batch SMU4DP001 Report No. SMG12800 Document No. VV-412229 , A20607B_10185 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.4.1 & KIIIA1 2.5.2 & KIIIA1 2.5.3 & KIIIA1 2.7.4 & KIIIA1 2.8.3.1 & KIIIA1 2.8.6.1 & KIIIA1 2.10.2
KCP 2.8.5.1	[redacted]	12/05/2015	A20607B - Physical and Technical Properties of Batch SMU4DP001 Report No. SMG12801 Document No. VV-412228 , A20607B_10183 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.1 & KIIIA1 2.4.2 & KIIIA1 2.8.2 & KIIIA1 2.8.3.1 & KIIIA1

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
								2.8.5.2 & KIIIA1 2.8.8.2 & KIIIA1 2.10.1
KCP 2.8.7	[redacted]	12/05/2015	A20607B - Physical and Technical Properties of Batch SMU4DP001 Report No. SMG12801 Document No. VV-412228 , A20607B_10183 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.1 & KIIIA1 2.4.2 & KIIIA1 2.8.2 & KIIIA1 2.8.3.1 & KIIIA1 2.8.5.2 & KIIIA1 2.8.8.2 & KIIIA1 2.10.1
KCP 2.10	[redacted]	12/05/2015	A20607B - Physical and Technical Properties of Batch SMU4DP001 Report No. SMG12801 Document No. VV-412228 , A20607B_10183 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.1 & KIIIA1 2.4.2 & KIIIA1 2.8.2 & KIIIA1 2.8.3.1 & KIIIA1 2.8.5.2 & KIIIA1 2.8.8.2 & KIIIA1 2.10.1

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 2.10	[redacted]	12/05/2015	A20607B - Physico-Chemical Characteristics of Batch SMU4DP001 Report No. SMG12800 Document No. VV-412229 , A20607B_10185 Test Facility Syngenta Biosciences Pvt. Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 2.4.1 & KIIIA1 2.5.2 & KIIIA1 2.5.3 & KIIIA1 2.7.4 & KIIIA1 2.8.3.1 & KIIIA1 2.8.6.1 & KIIIA1 2.10.2
KCP 5.1.1	[redacted]	26/06/2014	A20607B - Determination of Sedaxane, Fludioxonil and Metalaxyl-M in Formulation FS (015/022.5/015) Report No. 300021938 Document No. VV-128321 , A20607B_10177 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIIIA1 5.2.2
KCP 5.1.1	[redacted]	17/09/2014	A20607B - Validation of Analytical Method ST-35/1 Report No. CHMU140402 Document No. VV-412231 , A20607B_10187 Test Facility Syngenta Crop Protection GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 5.2.2
KCP 5.1.1	[redacted]	30/03/2015	A20607B - Determination of CGA329351 and CGA351920 in sedaxane/fludioxonil/metalaxyl-M FS (015/022.5/015) by chiral HPLC Report No. 300036892 Document No. VV-128322 , A20607B_10181 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	Y KIIIA1 5.2.2

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 5.1.1	[redacted]	09/07/2015	A20607B - Validation of Analytical Method STA-35/2 Report No. CHMU150540 Document No. VV-413006 , A20607B_10208 Test Facility Syngenta Crop Protection GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 5.2.2
KCP 5.1.1	[redacted]	11/12/2014	A9651D - Analytical Method SD-1751/1 Report No. 300021240 Document No. VV-128413 , A9651D_10487 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	N	-	SYN	N
KCP 5.1.1	[redacted]	25/11/2014	A9651D - Validation Analytical Method SD-1751/1 Report No. CHMU140410 Document No. VV-411110 , A9651D_10488 Test Facility Syngenta Crop Protection GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.1	[redacted]	04/05/2020	Statement on Validation of the Analytical Method SD-1751/1 for the determination of CGA72649 and CGA363736 in A20607B sedaxane/fludioxonil/metalaxyl-M FS (015/022.5/015) Report No. N/A Document No. VV-854722 Test Facility Syngenta Crop Protection Munchwilen AG GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	[redacted]	29/06/2006	Fludioxonil (CGA173506): Validation of Residue Analytical Method REM 133.06 for the determination of Residues in Crops. Final Determination by LC-MS/MS Report No. RJ3773B 05-S604 Document No. VV-337212 , CGA173506/6933 Test Facility Syngenta - Jealott's Hill International GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	[redacted]	19/05/2014	Fludioxonil - Validation of the Analytical Method for the Determination of Fludioxonil residues in Peas (seeds and	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			haulm) Report No. B3113 Document No. VV-407927 , CGA173506_11705 Test Facility Anadiag SA GLP Unpublished					
KCP 5.1.2	[redacted]	23/01/2012	Cyprodinil and Fludioxonil - Residue study on Cauliflower in Northern France, Poland and United Kingdom in 2010 Report No. R B0074 Document No. VV-401158 , A9219B_11593 Test Facility Anadiag SA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	[redacted]	30/06/2006	Analytical Method for the determination of Residues of Fludioxonil (CGA173506) in Crop Matrices. Final Determination by LC-MS/MS Report No. REM 133.06 Document No. VV-124731 , CGA173506/6932 Test Facility Syngenta - Jealott's Hill International Not GLP Unpublished	N	N	-	SYN	N
KCP 5.1.2	[redacted]	01/10/2015	Sedaxane - Residue Study following seed treatment with A20110E, on Potato in Southern France and Spain in 2014 Report No. S14-01326 Document No. VV-413257 , A20110E_10061 Test Facility Eurofins Agroscience Services Ltd GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.1.2	[redacted]	16/01/2018	Fludioxonil (CGA173506) - Validation of Analytical Method REM133.06 for the Determination of Residues of Fludioxonil in multiple crops Report No. R B7376 Document No. VV-469007 , CGA173506_12273 Test Facility Anadiag SA GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP	[redacted]	15/06/2016	Metalaxyl-M – Validation of the QuEChERS Multiple Resi-	N	Y	New study never submitted	SYN	N

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
5.2.1			due Method in Hops and Cocoa Beans Report No. RES-00055 Document No. VV-465427 , CGA329351_11743 Test Facility ResChem Analytical Limited GLP Unpublished			before to this country		
KCP 5.2.1	[redacted]	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	[redacted]	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	Y	New study never submitted before to this country	SYN	N
KCP 5.2.1	[redacted]	19/09/2019	SYN524464 - Independent Laboratory Validation of the QuEChERS Method for the Determination of Residues of SYN508210 and SYN508211 in Crop Matrices by LC-MS/MS Report No. 20190112 Document No. VV-619363 , SYN508210_10296 Test Facility Innovative Environmental Services GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.2.1	[redacted]	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	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			GLP Unpublished					
KCP 5.2.1	[redacted]	07/01/2014	Metalaxyl-M – Independent Laboratory Validation (ILV) of an Analytical Method for Determination of Residues of Metalaxyl-M in Crops Report No. S11-03712 Document No. VV-407367 , CGA329351_11643 Test Facility Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.2.2	[redacted]	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	[redacted]	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
KCP 5.2.2	[redacted]	02/04/2009	Fludioxonil - Magnitude of residues in animal tissues following repeated oral administration to the laying hen Report No. [redacted] Document No. VV-383645 , CGA173506_11440 Test Facility [redacted] GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 5.2.2	[redacted]	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 Report No. GRM025.03A Document No. VV-127758 , CGA173506_11402 Test Facility ADME - Bioanalyses Not GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.2.2	[redacted]	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	Y	New study never submitted before to this country	SYN	N
KCP 5.2.2	[redacted]	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 Agroscience Services Chem GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.2.5	[redacted]	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	[redacted]	04/04/2016	Fludioxonil – Independent Laboratory Validation (ILV) of Analytical Method GRM025.01A for the Determination of	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			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 GLP Unpublished					
KCP 5.2.5	[redacted]	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	[redacted]	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 Agroscience Services Chem SAS GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 5.2.5	[redacted]	23/09/2019	SYN524464 - Independent Laboratory Validation of Analytical Method GRM023.06A for the Determination of Residues of SYN508210 and SYN508211 and the Metabolites CSCC210616, CSCD465008 and CSAA798670 in Water Report No. S18-05320 Document No. VV-619368 , SYN508210_10298 Test Facility Eurofins Agroscience Services Chem GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCP 7.1.1	[redacted]	20/03/2015	Sedaxane/Fludioxonil/Metalaxyl-M FS (A20607B) - Acute Oral Toxicity Study in the Rat (Up and Down Procedure) Report No. [redacted] Document No. VV-411770 , A20607B_10042	Y	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 7.1.1

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Test Facility [redacted] GLP Unpublished					
KCP 7.1.2	[redacted]	05/03/2015	Sedaxane/Fludioxonil/Metalaxyl-M FS (A20607B) - Acute Dermal Toxicity Study in Rats Report No. [redacted] Document No. VV-411280 , A20607B_10029 Test Facility [redacted] GLP Unpublished	Y	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 7.1.2
KCP 7.1.3	[redacted]	30/03/2015	Sedaxane/Fludioxonil/Metalaxyl-M FS (A20607B) – Acute Inhalation Toxicity Study (Nose-Only) in the Rat Report No. [redacted] Document No. VV-411785 , A20607B_10049 Test Facility [redacted] GLP Unpublished	Y	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 7.1.3
KCP 7.1.4	[redacted]	10/02/2015	Sedaxane/Fludioxonil/Metalaxyl-M FS (A20607B) - Prima-ry Skin Irritation Study in Rabbits Report No. [redacted] Document No. VV-411560 , A20607B_10015 Test Facility [redacted] GLP Unpublished	Y	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 7.1.4
KCP 7.1.5	[redacted]	25/02/2015	Sedaxane/Fludioxonil/Metalaxyl-M FS (A20607B) - Acute Eye Irritation Study in Rabbits Report No. [redacted] Document No. VV-411384 , A20607B_10032 Test Facility [redacted] GLP Unpublished	Y	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 7.1.5
KCP 7.1.6	[redacted]	12/03/2015	Sedaxane/Fludioxonil/Metalaxyl-M FS (A20607B) –Local Lymph Node Assay in the Mouse – Individual Method Report No. 41403291 Document No. VV-411911 , A20607B_10037 Test Facility [redacted] GLP	Y	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 7.1.6

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Unpublished					
KCP 9.1.1	[redacted]	26/07/2013	Sedaxane - Calculation of Kinetic Endpoints for Metabolite CSCD728931 for Modelling Purposes from Laboratory Data According to FOCUS Kinetic Guidelines Report No. RAJ1002B Document No. VV-628062 , SYN546282_10003 Test Facility Syngenta - Jealott's Hill Not GLP Unpublished	N	N	-	SYN	Y KIIIA1 9.1.1
KCP 9.1.1	[redacted]	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 Unpublished	N	N	-	SYN	N
KCP 9.1.1	[redacted]	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 9.2.4	[redacted]	02/06/2020	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 Sugar beet Report No. 19-016-150-6 Document No. VV-858626 Test Facility TSG Consulting Not GLP Unpublished	N	N	-	SYN	N
KCP 9.2.4	[redacted]	26/05/2020	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	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			to Sugar beet Report No. 19-016-150-7 Document No. VV-858628 Test Facility TSG Consulting Not GLP Unpublished					
KCP 9.2.4	[redacted]	22/05/2020	A Leaching Assessment for Sedaxane and its Soil Metabo-lites CSAA798670, CSCD465008 and CSCD728931 Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Sugar beet Report No. 19-016-150-8 Document No. VV-858630 Test Facility TSG Consulting Not GLP Unpublished	N	N	-	SYN	N
KCP 10.1.1	[redacted]	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 [redacted] GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 10.1.1	[redacted]	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 [redacted] GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 10.1.1	[redacted]	07/05/1996	The reproductive toxicity test of CGA 24705 in Northern Bobwhite (Colinus virginianus) Report No. 029508 Document No. VV-371001 , CGA24705/2591 Test Facility [redacted] GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
KCP 10.1.1	[redacted]	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 [redacted] GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCP 10.1.1.2	[redacted]	16/12/2002	Acceptance of Sugar Beet Pills by Birds - Field Monitoring of Birds in the Netherlands Report No. BAR/FS008 M-073901-02-1 E308 2083-4 Document No. VV-339631 , N/1158 Test Facility Bayer AG Not GLP Unpublished	N	N	-	ETL_blank	Y KIIIA1 10.1.7
KCP 10.1.2.1	[redacted]	20/03/2015	Sedaxane/Fludioxonil/Metalaxyl-M FS (A20607B) - Acute Oral Toxicity Study in the Rat (Up and Down Procedure) Report No. [redacted] Document No. VV-411770 , A20607B_10042 Test Facility [redacted] GLP Unpublished	Y	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 7.1.1
KCP 10.2.1	[redacted]	15/01/2015	Sedaxane/Fludioxonil/Metalaxyl-M (A20607B) – Toxicity to the Water Flea Daphnia magna Straus under Laboratory Conditions (Acute Immobilisation Test – Static) Report No. S14-04365 Document No. VV-411275 , A20607B_10013 Test Facility Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.2.2.2
KCP 10.2.1	[redacted]	17/02/2015	Sedaxane/Metalaxyl-M/Fludioxonil FS (A20607B) – Toxicity to the Single Cell Green Alga Pseudokirchneriella subcapitata under Laboratory Conditions Report No. S14-04367 Document No. VV-411345 , A20607B_10028 Test Facility Eurofins Agroscience Services EcoChem GmbH	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.2.2.3

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			GLP Unpublished					
KCP 10.2.1	[redacted]	01/12/2014	Sedaxane/Metalaxyl-M/Fludioxonil FS (A20607B) – Toxicity to the Rainbow Trout Oncorhynchus mykiss under Laboratory Conditions (Acute Toxicity Test – Static) Report No. [redacted] Document No. VV-410902 , A20607B_10003 Test Facility [redacted] GLP Unpublished	Y	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.2.2.1
KCP 10.3.1.1.1	[redacted]	07/01/2015	Sedaxane/Metalaxyl-M/Fludioxonil FS (A20607B) – Acute Oral and Contact Toxicity to the Honey Bee, Apis mellifera L. under Laboratory Conditions Report No. S14-04368 Document No. VV-411251 , A20607B_10012 Test Facility Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.4.2.1
KCP 10.3.1.1.2	[redacted]	07/01/2015	Sedaxane/Metalaxyl-M/Fludioxonil FS (A20607B) – Acute Oral and Contact Toxicity to the Honey Bee, Apis mellifera L. under Laboratory Conditions Report No. S14-04368 Document No. VV-411251 , A20607B_10012 Test Facility Eurofins Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.4.2.1
KCP 10.3.2.2	[redacted]	16/12/2014	Sedaxane/Fludioxonil/Metalaxyl-M (A20607B) – A rate response extended laboratory bioassay of the effects of fresh residues on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) Report No. SYN-14-89 Document No. VV-411004 , A20607B_10007 Test Facility Mambo-Tox Ltd. GLP	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.5.2

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Unpublished					
KCP 10.3.2.2	[redacted]	22/01/2015	Sedaxane/Fludioxonil/Metalaxyl-M (A20607B) – Chronic toxicity to the rove beetle Aleochara bilineata Gyll. under extended laboratory conditions Report No. 14 10 48 079 A Document No. VV-411399 , A20607B_10014 Test Facility BioChem agrar GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.5.2
KCP 10.3.2.2	[redacted]	09/12/2014	Sedaxane/Fludioxonil/Metalaxyl-M FS (A20607B) – A rate-response extended laboratory bioassay of the effects of fresh residues on the parasitic wasp Aphidius rhopalosiphi (Hymenoptera, Braconidae) Report No. SYN-14-88 Document No. VV-410983 , A20607B_10005 Test Facility Mambo-Tox Ltd. GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.5.2
KCP 10.4.1.1	[redacted]	16/02/2015	Sedaxane/Fludioxonil/Metalaxyl-M (A20607B) – Sublethal Toxicity to the Earthworm Eisenia fetida in Artificial Soil with 5 % Peat Report No. 14 10 48 263 S Document No. VV-411595 , A20607B_10026 Test Facility BioChem agrar GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.6.3
KCP 10.4.2	[redacted]	16/02/2015	Sedaxane/Fludioxonil/Metalaxyl-M (A20607B) – Effects on the Reproduction of the Collembolan Folsomia candida Report No. 14 10 48 264 S Document No. VV-411596 , A20607B_10027 Test Facility BioChem agrar GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.6.6
KCP 10.4.2	[redacted]	18/12/2014	Sedaxane/Fludioxonil/Metalaxyl-M (A20607B) – Effects on the reproduction of the predatory mite Hypoaspis aculeifer Report No. 14 10 48 262 S Document No. VV-411210 , A20607B_10011	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.6.6

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Test Facility BioChem agrar GLP Unpublished					
KCP 10.5	[redacted]	16/12/2014	Sedaxane/Fludioxonil/Metalaxyl-M (A20607B) – Effects on the activity of soil microflora (nitrogen and carbon transformation test) Report No. 14 10 48 079 C/N Document No. VV-411005 , A20607B_10008 Test Facility BioChem agrar GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 10.7.1
KCA1 6.3.1	[redacted]	10/05/2019	Fludioxonil - Residue Study on Sugarbeet in Northern France, Germany, Poland and Hungary in 2018, Treated Seed Report No. S18-02806 Document No. VV-472100 , A20607B_10339 Test Facility Eurofins Agroscience Services Chem GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.1	[redacted]	07/05/2019	Fludioxonil - Residue Study on Sugarbeet in Italy, Spain and Bulgaria in 2018, Treated Seed Report No. S18-02807 Document No. VV-472013 , A20607B_10340 Test Facility Eurofins Agroscience Services Chem GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 6.3.1	[redacted]	28/02/2005	Fludioxonil (CGA173506): Residue Study in or on Sugar Beet in Switzerland - Seed Treatment Report No. 04-0315 Document No. VV-333191 , CGA173506/6254 Test Facility ADME - Bioanalyses GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 8.3.1
KCA1 6.3.1	[redacted]	22/07/2005	Fludioxonil (CGA173506) in or on Sugar Beet in Italy - Seed Treatment Report No. 04-0313 Document No. VV-333622 , CGA173506/6488	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 8.3.1

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Test Facility ADME - Bioanalyses GLP Unpublished					
KCA1 7.1.2.2.1	[redacted]	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	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 9.2.1
KCA1 8.1.1.3	[redacted]	06/10/2015	Fludioxonil – A Reproduction Study with the Northern Bobwhite Report No. [redacted] Document No. VV-414222 , CGA173506_11828 Test Facility [redacted] GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCA1 8.2.2.2	[redacted]	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-414235 , CGA173506_51493 Test Facility [redacted] GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCA1 8.2.5.1	[redacted]	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
KCA1 8.3.1.2	[redacted]	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	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			GLP Unpublished					
KCA1 8.3.1.3	[redacted]	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	N	-		N
KCA1 8.3.1.3	[redacted]	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 Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA1 8.4.2	[redacted]	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
KCA2 5.4.2	[redacted]	15/09/2017	CGA226048 - Oral (Gavage) Mouse Micronucleus Test Report No. [redacted] Document No. VV-468462 , CGA226048_10000 Test Facility [redacted] GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N
KCA2 6.3.1	[redacted]	12/04/2019	Metalaxyl-M - Residue Study on Sugar Beet in Italy, Spain and Bulgaria in 2018 - Treated Seed Report No. S18-02613 Document No. VV-471744 , A9642C_11061 Test Facility Eurofins Agroscience Services Chem 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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			GLP Unpublished					
KCA2 6.3.1	[redacted]	28/03/2019	Metalaxyl-M - Residue Study on Sugar Beet in Germany, Northern France and Poland in 2018 - Treated Seed Report No. S18-02612 Document No. VV-471699 , A9642C_11060 Test Facility Eurofins Agroscience Services Chem GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA2 8.3.1.2	[redacted]	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 Agroscience Services EcoChem GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA2 8.3.1.3	[redacted]	14/01/2016	Metalaxyl-M SL (A13947A) – Honey Bee (Apis mellifera L.) Larval Toxicity Test (Repeated Exposure) Report No. S15-02457 Document No. VV-415529 , A13947A_11455 Test Facility Eurofins Agroscience Services GmbH GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA3 6.3.1	[redacted]	14/08/2014	Sedaxane - Residue Study, Following Seed Treatment, on Sugar Beet in the United Kingdom and Northern France in 2013 Report No. S13-01026 Document No. VV-409594 , A16148F_10993 Test Facility Eurofins Agroscience Services Ltd GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 8.3.1
KCA3 6.3.1	[redacted]	13/08/2014	Sedaxane - Residue Study, Following Seed Treatment, on Sugar Beet in Spain and Italy in 2013 Report No. S13-01027 Document No. VV-409615 , A16148F_10994	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 8.3.1

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Test Facility Eurofins Agroscience Services Ltd GLP Unpublished					
KCA3 6.5.3	[redacted]	03/10/2012	SYN524464 500FS (A16148C) - Magnitude of the Residues in Potato Following Seed Treatment Application USA 2011 Report No. 120420|TK0049813 Document No. VV-507917 , A16148C_50136 Test Facility Syngenta Crop Protection GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA3 7.1.2.1.2	[redacted]	18/11/2013	SYN546282 – Rate of Degradation of 14C-SYN546282 Report No. 20120177 Document No. VV-406128 , SYN546282_10001 Test Facility Innovative Environmental Services GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 9.1.1
KCA3 7.1.3.1.2	[redacted]	07/08/2013	SYN546282 - Adsorption/Desorption Properties of 14C-SYN546282 in Five Soils Report No. 20120176 Document No. VV-405131 , SYN546282_10000 Test Facility Innovative Environmental Services GLP Unpublished	N	Y	Data protection started with MAPP 18588 on 19.06.2018; Expiry date 19.06.2028	SYN	Y KIIIA1 9.3
KCA3 8.3.1.2	[redacted]	14/02/2019	Sedaxane - 10-Day Oral Toxicity Test with the Adult Honey Bee (Apis mellifera) Report No. 1781.7269 Document No. VV-547643 , SYN524464_51134 Test Facility Smithers Viscient GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA3 8.3.1.2	[redacted]	30/11/2015	Sedaxane FS (A16148C) – Chronic toxicity to the honeybee Apis mellifera L. in a 10 day continuous laboratory feeding study Report No. 15 10 48 151 B Document No. VV-414710 , A16148C_10597 Test Facility BioChem agrar GLP	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	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used Y/N If yes, for which data point?
			Unpublished					
KCA3 8.3.1.3	[redacted]	07/04/2016	Sedaxane FS (A16148C) – Chronic toxicity to the honeybee larvae Apis mellifera L. under laboratory conditions (in vitro) Report No. 15 10 48 150 B Document No. VV-462974 , A16148C_10610 Test Facility BioChem agrar GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA3 8.3.1.3	[redacted]	26/02/2019	Sedaxane - Honey Bee (Apis mellifera) Larval Toxicity Test, Repeated Exposure Report No. 1781.7267 Document No. VV-547665 , SYN524464_51135 Test Facility Smithers Viscient GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA3 8.4.2	[redacted]	30/08/2018	CA4312 – Effects on the reproduction of the collembolan Flosomia candida Report No. 18 48 TCC 0033 Document No. VV-470598 , CA4312_10924 Test Facility BioChem agrar GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA3 8.4.2	[redacted]	17/10/2018	R958945 – Effects on the Reproduction of the Predatory Mite Hypoaspis aculeifer Report No. 18 48 THC 0039 Document No. VV-470516 , R958945_11298 Test Facility BioChem agrar GLP Unpublished	N	Y	New study never submitted before to this country	SYN	N
KCA3 8.4.2	[redacted]	12/09/2018	CA4312 – Effects on the Reproduction of the Predatory Mite Hypoaspis aculeifer Report No. 18 48 THC 0038 Document No. VV-470515 , CA4312_10925 Test Facility BioChem agrar 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

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

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in **this** MS: Data protection started with: <insert authorization number of first authorization>	Owner	
KCA2 5.4.2	[redacted]	27/01/2015	Metalaxyl-M - Oral (Gavage) Mouse Micronucleus Test Report No. [redacted] Document No. VV-411540 , CGA329351_11683 Test Facility [redacted] GLP Unpublished	Y	Y	New study never submitted before to this country	SYN	N

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

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