

# DRAFT REGISTRATION REPORT

## Part B

### Section 1: Identity

### Section 2: Physical and chemical properties

### Section 4: Further information

Detailed summary of the risk assessment

Product code: A9873C

Product name: Wakil XL

Chemical active substances:

Cymoxanil, 100 g/kg

Fludioxonil, 50 g/kg

Metalaxyl-M, 169.6 g/kg

~~United Kingdom~~

Great Britain (GB)

## NATIONAL ASSESSMENT

~~(Renewal of authorisation)~~

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

Applicant: Syngenta

Submission date: 21/10/2021

Finalisation date: 31/01/2024

## Version history

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

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

No equivalence assessment is required.

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

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

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

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

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

<sup>1</sup> 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

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.

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 1<sup>st</sup> 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".

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substances.

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

‘Wakil XL’, this case may not be accepted for future products.

A low temperature storage stability data is not required and has not been submitted.

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

#### **Tank Mixing**

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

#### **Compliance with FAO specifications:**

A FAO specification for metalaxyl-M is not available

#### **Formulation used for tests**

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


#### **Conclusion:**

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

## **1 Section 1: Identity of the plant protection product**

### **1.1 Applicant (KCP 1.1)**

Name: SYNGENTA CROP PROTECTION AG

Contact:   
Syngenta Crop Protection AG  
Rosentalstrasse 67  
CH-4058 Basel  
Switzerland

Telephone Nr: 

Fax number: 

E-mail: 

## 1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

### 1.2.1 Producer(s) of the preparation

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

### 1.2.2 Producer(s) of the active substances

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

### 1.2.3 Statement of purity (and detailed information on impurities) of the active substances

#### 1.2.3.1 Cymoxanil

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	'Wakil XL' was not the representative product for the approval of metalaxyl-M. 'Wakil XL' has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Wakil XL' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.

Test Substance	EU agreed minimum purity Reference: COMMISSION DIRECTIVE 2008/125/EC
Cymoxanil	970 g/kg

#### Pure Cymoxanil in A9873C

content of pure active substance:	100 g/kg	10 % w/w
FAO limits :	90 - 110 g/kg	9.0 – 11.0 % w/w

#### Technical Cymoxanil in A9873C

at a minimum purity of the technical active substance of 97.0 % w/w.		
content of technical active substance:	103 g/kg	10.3 % w/w
FAO limits :	97 - 109 g/kg	9.7 – 10.9 % w/w

#### 1.2.3.2 Fludioxonil

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY
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<b>Name of authority</b>	<b>HSE Chemicals Regulation Division (CRD), UK</b>
<b>Reviewer's comments</b>	'Wakil XL' was not the representative product for the approval of metalaxyl-M. 'Wakil XL' has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Wakil XL' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.

<b>Test Substance</b>	<b>EU agreed minimum purity Reference: COMMISSION DIRECTIVE 2007/76/EC</b>
<b>Fludioxonil</b>	950 g/kg

#### Pure Fludioxonil in A9873C

<b>content of pure active substance:</b>	<b>50.0 g/kg</b>	<b>5.00 % w/w</b>
FAO limits :	45.0 – 55.0 g/kg	4.50 – 5.50 % w/w

#### Technical Fludioxonil in A9873C

<b>at a minimum purity of the technical active substance of 95.0 % w/w.</b>		
<b>content of technical active substance:</b>	<b>52.6 g/kg</b>	<b>5.26 % w/w</b>
FAO limits :	47.4 -57.9 g/kg	4.74 – 5.79 % w/w

### 1.2.3.3 Metalaxyl-M

<b>EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY</b>	
<b>Name of authority</b>	<b>HSE Chemicals Regulation Division (CRD), UK</b>
<b>Reviewer's comments</b>	<p>Metalaxyl-M is an approved active substance. According to the GB Active Substance Approvals Register and Commission Implementing Regulation (EU) 2020/617 the following conditions of approval apply:</p> <p>Minimum purity: 920 g/kg                      Maximum relevant impurities: 0.5 g/kg 2,6-dimethylphenylamine                      1.0 g/kg 4-methoxy-5-methyl-5H-[1,2]oxathiole 2,2-dioxide                      0.18 g/kg 2-[(2,6-dimethyl-phenyl)-(2-methoxyacetyl)-amino]-propionic acid 1-methoxycarbonyl-ethyl ester</p> <p>The applicant's source(s) of technical material used in 'A9873C' complies with the conditions of approval.</p> <p>The declared content of metalaxyl-M in 'A9873C' is in agreement with that declared on the CRD application form. The declared tolerance limits for the product are in agreement with the FAO tolerances for formulated products</p>

Test Substance	EU agreed minimum purity Reference: IMPLEMENTING REGULATION (EU) 2020/617
<b>Metalaxyl-M</b>	920 g/kg
<b>Relevant impurities</b>	
2,6-dimethylphenylamine (CGA72649)	≤ 0.5 g/kg
4-methoxy-5-methyl-5H-[1,2] oxathiole 2,2-dioxide (CGA363736)	≤ 1 g/kg
2-[(2,6-dimethyl-phenyl)-(2- methoxyacetyl)-amino]-propionic acid 1-methoxycarbonyl- ethyl ester (CGA226048)	≤ 0.18 g/kg

### Pure Metalaxyl-Min A9873C

content of pure active substance:	169.6 g/kg	17.0 % w/w
FAO limits :	160 - 180 g/kg	16.0 – 18.0 %w/w

### Technical Metalaxyl-M in A9873C

at a minimum purity of the technical active substance of 92.0 % w/w.		
content of technical active substance:	184 g/kg	18.4 % w/w
FAO limits :	173 – 195 g/kg	17.3 – 19.5 %w/w

An assessment of equivalence is not required since sources for the active substance have been approved previously.

## 1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Wakil XL  
 Trade name: Please refer to Registration Report Part A for the relevant country  
 Company code number: A9873C

## 1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

### 1.4.1 Composition of the plant protection product (KCP 1.4.1)

The product A9873C was not evaluated previously as a representative formulation (same uses and same GAPs) during the EU review of the active substances cymoxanil, fludioxonil and metalaxyl-M.

The content of cymoxanil, fludioxonil and metalaxyl-M in A9873C is given under point 1.2.3

The maximum amount of relevant impurities has been addressed in point 1.2.3.

Information on the variants is addressed under point 1.4.2.

Information on the formulants including safeners and synergists is confidential and is included in **Part C (Confidential information)**.

### 1.4.2 Information on the active substances (KCP 1.4.2)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	The applicant's summary of the information on cymoxanil, fludioxonil and metalaxyl-M is correct. Additional information on the EC number has been added in green.

**Table 1.4.2-1: Information on cymoxanil**

Type	Name/Code Number	
ISO common name	Cymoxanil/ASF331	Variant: not relevant
CAS No.	57966-95-7	
EC No.	<del>Not available</del> 261-043-0	
CIPAC No.	419	

**Table 1.4.2-2: Information on Fludioxonil**

Type	Name/Code Number	
ISO common name	Fludioxonil/CGA173506	Variant: not relevant
CAS No.	131341-86-1	
EC No.	<del>Not available</del> 603-476-3	
CIPAC No.	131341-86-1	

**Table 1.4.2-3: Information on Metalaxyl-M**

Type	Name/Code Number	
ISO common name	Metalaxyl-M/CGA329351	Variant: not relevant
CAS No.	70630-17-0	
EC No.	<del>not available</del> 615-135-6	
CIPAC No.	580	

### 1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Information on the formulants including safeners and synergists is confidential and is provided separately in **Part C (Confidential information)**.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's	'A9873C' does not contain any safeners or synergists

comments	
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### 1.5 Type and code of the plant protection product (KCP 1.5)

Type: Water dispersible granule

[Code: WG]

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	The type and code are in agreement with the international FAO descriptions.

### 1.6 Function (KCP 1.6)

Fungicide.

## 2 Section 2: Physical, chemical and technical properties of the plant protection product

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	<p>'Wakil XL' was not the representative product for the approval of metalaxyl-M. 'Wakil XL' has been assessed in the current evaluation as a representative product for the Article 7 amendment to the GB approval for metalaxyl-M. As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Wakil XL' is not to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and cymoxanil have not been considered further.</p> <p>A number of the studies below have previously been assessed and found to be acceptable, for the current evaluation, the decision on the studies acceptability has not been reopened, this is in view of the above statement. For a future product authorisation, where the intention is to place the product on the market, the previously evaluated studies may be revisited in light of updated/new guidance.</p> <p>'Wakil XL' is a WG formulation containing 169.6 g/kg metalaxyl-M, 100 g/kg cymoxanil and 50 g/kg fludioxonil.</p> <p>The intended in -use concentration of product is 11.4% to 54%. It is not noted on what basis this means, i.e. w/v or v/v. As the product is not to be authorised, and as such has no proposed label, the studies have not been strictly evaluated in relation to the in use concentration – this may be revisited for a future product authorisation.</p> <p>All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable (<b>studies previously evaluated have not been reopened</b>). 'Wakil XL' is a red solid. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of <math>214 \pm 5^{\circ}\text{C}</math>. The pH of the 1% dilution of the preparation is 6.0.</p> <p>Acceptable physical, chemical and technical data have been provided indicating that the product fulfils the requirements of a WG formulation.</p> <p>Acceptable accelerated (2 weeks at <math>54^{\circ}\text{C}</math>, and others) storage stability data have been submitted indicating the product does retain its technical properties during storage. Data on the content of metalaxyl-M, cymoxanil and fludioxonil before and after accelerated storage shows no significant degradation.</p> <p>The content of the relevant impurities CGA72649, CGA363736 and CGA226048 have not been determined pre- or post- storage. The applicant submitted a case with regards to the inability for the metabolites to form on storage for a similar application containing metalaxyl-M (COP 202001452). The applicants case for CGA72649 and CGA 363736 was accepted. The applicants case with regards to CGA226048 was not accepted, HSE is of the view that there is potential for CGA226048 to form on storage, see data requirements below. However, as this article 7 seeks to remove the classification of CGA226048 as a relevant impurity, no further information will be requested at this time. This may be reopened for future applications if it is decided that the metabolite is to remain relevant. Additionally, the applicants case with respect to the potential (or lack thereof) for formation of CGA72649 and CGA 363736 on storage was accepted on the basis of the composition of 'Wakil XL', this case may not be accepted for future products.</p>

A low temperature storage stability study is not required and has not been submitted.

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

#### **Tank Mixing**

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

#### **Compliance with FAO specifications:**

A FAO specification for metalaxyl-M is not available

#### **Formulation used for tests**

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

#### **Conclusion:**

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of red solid with a weak odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of 214 °C. In aqueous solution, it has a pH value around 6.0. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a WG formulation.

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

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

According to Regulation (EC) No. 1272/2008 no specific labelling or classification is proposed based on the measured physico-chemical properties of A9873C

#### **Notifier Proposals for Risk and Safety Phrases (KCP 12)**

According to Regulation (EC) No. 1272/2008 no specific labelling or classification is proposed based on the measured physico-chemical properties of product A9873C

#### **Compliance with FAO specifications:**

There is no FAO specification for A9873C.

### **Formulation used for tests**

A9873C.

**Table 2-1: Physical, chemical and technical properties of the plant protection product**

All tests have been performed under GLP, except where mentioned.

All tests were conducted using material from batches:

KWL0K111 (A9873C) containing a mean of 98.8 g/kg cymoxanil, 48.3 g/kg fludioxonil, 170 g/kg metalaxyl-M (██████, 2011; Syngenta File No A9873C\_10212-VV-400774).

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual and organoleptic test	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	Red solid with a weak odour	N	██████, 2012 A9873C_10219 VV-400779	Acceptable.
Explosive properties (KCP 2.2.1)	EEC A.14	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	Not an explosive substance	Y	██████, 2012 A9873C_10215 VV-400776	Acceptable.
Oxidizing properties (KCP 2.2.2)	Theoretical assessment		Not an oxidising substance	Y	██████, 2012 A9873C_10215 VV-400776	Acceptable
Flash point (KCP 2.3.1)			Not applicable (solid)	---		Noted
Flammability (KCP 2.3.2)	EEC A.10	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	Not classified in terms of its burning characteristics	Y	██████, 2012 A9873C_10215 VV-400776	Acceptable
Self-heating (KCP 2.3.3)	EEC A.16	cymoxanil 98.8 g/kg	214 ± 5°C	Y	██████, 2012	Acceptable.



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG			<i>A9873C_10215</i> <i>VV-400776</i>	
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	Acidity: 0.21 % (calculated as H <sub>2</sub> SO <sub>4</sub> )	Y	██████, 2012 <i>A9873C_10214</i> <i>VV-400775</i>	Not applicable as pH is between 4 and 7
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	pH 1 % suspension in water: 6.0	Y	██████, 2012 <i>A9873C_10214</i> <i>VV-400775</i>	Acceptable.
Viscosity (KCP 2.5.1)			Not applicable			
Surface tension (KCP 2.5.2)			Not applicable			
Relative density (KCP 2.6.1)			Not applicable			
Bulk density (KCP 2.6.2)	CIPAC MT 186	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	- Pour density: 0.579 g/mL - Tap density: 0.630 g/mL	Y	██████, 2012 <i>A9873C_10214</i> <i>VV-400775</i>	Acceptable
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	The formulation undergoes no significant physical or chemical degradation during storage at 54°C in packaging made of HDPE for 14 days. See appendix 3	N	██████, 2012 <i>VV-406461</i>	Acceptable, previous conclusion:  <i>The formulation is stable after storage for 2 weeks at 54°C in glass container</i>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>Validation data of the analytical method were provided in section 2</p> <p>Seed loading properties have not been tested for the PPP following storage. Nevertheless given all the other physical properties are acceptable then such data are not required after storage</p>
Stability after storage for other periods and/or temperatures (KCP 2.7.2)		4.86% fludioxonil, 17.9% metalaxyl-M, 10.4% cymoxanil WG (A9873C)	<p>The formulation undergoes no significant physical or chemical degradation during storage at 30°C in packaging made of LDPE, Polypropylene for 18 weeks.</p> <p>See appendix 4 and 5</p>	N	<p>██████████ <b>1999 VV-117175</b></p> <p>██████████ <b>1999 VV-111577</b></p>	<p>Previous conclusion:</p> <p>No significant physical or chemical change during storage in all container types.</p> <p>This conclusion is valid for all container types, except glass, for which no method validation data was provided.</p>
Minimum content after heat stability testing (KCP 2.7.3)			Not relevant			
Effect of low temperatures on			Not relevant			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
stability (KCP 2.7.4)						
Ambient temperature shelf life (KCP 2.7.5)	GIFAP Monograph 17	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	The formulation undergoes no significant physical or chemical degradation after storage at 20°C in packaging made of HDPE for 2 years.  See Appendix 6,7 and 8	Y	<p>██████████, 2014 VV-407964</p> <p>██████████ 2000, VV-285268</p> <p>██████████ 2000, VV-285269</p>	<p>Acceptable.</p> <p>As noted in the summary, further data may be required in future to support a full product authorisation.</p> <p>No details were provided on the content of the relevant impurities pre/post storage.</p> <p>The applicant submitted a case on the potential (or lack thereof) for the relevant impurities to form on storage for a previous product. The case that CGA72649 and CGA363736 are unlikely to be formed on storage is acceptable.</p> <p>The applicants case regarding CGA 226048 has not been accepted. See green box above.</p> <p>In addition to the</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>above, the applicants case highlighted that all relevant impurities can only be formed by the breakdown (or in the case of CGA 226048, the conjugation) of metalaxyl-M. As such, if any metabolites were formed, an observable decline of the metalaxyl-M content would be apparent. However, the ambient storage stability demonstrates that the content of metalaxyl-M post 2 year storage is different by a maximum of -1.7 %; therefore minimal breakdown is seen, the small difference may even be a result of the method. This further strengthens the case that the metabolites are unlikely to be formed on storage.</p> <p><b>For future uses, where stored seed is recommended for use in future growing seasons (i.e. retained,</b></p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						treated seed is recommended for use in the next, year or two), this claim must be supported by data, including but potentially not limited to distribution to seed and seed adhesion data.
Shelf life in months (if less than 2 years) (KCP 2.7.6)			Not applicable			
Wettability (KCP 2.8.1)	CIPAC MT 53.3	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	7 sec	N	██████, 2012 A9873C_10219 VV-400779	Acceptable
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	Concentration 60% in CIPAC water D: after 10s 0 mL after 1 min 0 mL after 3 min 0 mL after 12 min 0 mL  Concentration 10% in CIPAC water D: after 10s 14 mL after 1 min 0 mL after 3 min 0 mL	N	██████, 2012 A9873C_10219 VV-400779	Acceptable

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			after 12 min 0 mL			
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	<u><b>Gravimetrically</b></u> in CIPAC water D at 30°C after 30 min: concentration 60 %: 101% concentration 10 %: 90%  <u><b>A.I. Suspensibility</b></u> in CIPAC water D at 30°C after 30 min  <u><b>conc. 60 %:</b></u> - metalaxyl-M 100% - cymoxanil 100% - fludioxonil 100%  <u><b>conc. 10 %:</b></u> - metalaxyl-M 94% - cymoxanil 67% - fludioxonil 87%	N	██████, 2012 A9873C_10219 VV-400779	Acceptable.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 174	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	<u><b>Gravimetrically</b></u> in CIPAC water D: 96%	N	██████, 2012 A9873C_10219 VV-400779	
Dispersion stability (KCP 2.8.3.3)			Not applicable			
Degree of dissolution and			Not applicable			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
dilution stability (KCP 2.8.4)						
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 170	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	≥ 90% was retained on the 125 µm sieve ≤ 10% was retained on the 800 µm sieve	Y	██████, 2012 A9873C_10214 VV- 400775	Acceptable
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	Material retained on a 75 µm test sieve: < 0.01%	N	██████, 2012 A9873C_10219 VV-400779	Acceptable – concentration of test substance should be highest in use conc., the conc. of the test substance was not given.  The method guidelines state the highest in use conc. must be used. However, in this instance (as the product is not to be placed on the market), it is appropriate to request this information for a future product authorisation.  <b>Information on the concentration of the test item should be provided</b>
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg	Collected dust: 0.4 mg	Y	██████, 2012	Acceptable – interpretation: ‘nearly dust free’

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		A9873C WG			<i>A9873C_10214</i> <i>VV- 400775</i>	
Particle size of dust (KCP 2.8.5.2.2)			Not applicable			
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	Attrition resistance: 100%	N	██████, 2012 <i>A9873C_10219</i> <i>VV-400779</i>	Acceptable
Hardness and integrity (KCP 2.8.5.4)			Not applicable			
Emulsifiability (KCP 2.8.6.1)			Not applicable			
Emulsion stability (KCP 2.8.6.2)			Not applicable			
Re-emulsifiability (KCP 2.8.6.3)			Not applicable			
Flowability (KCP 2.8.7.1)	CIPAC MT 172	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	The item dropped through the 5 mm test sieve spontaneously	N	██████, 2012 <i>A9873C_10219</i> <i>VV-400779</i>	Acceptable
Pourability (KCP 2.8.7.2)			Not applicable			
Dustability following accelerated			Not applicable			



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
storage (KCP 2.8.7.3)						
Physical compatibility of tank mixes (KCP 2.9.1)			Not applicable			
Chemical compatibility of tank mixes (KCP 2.9.2)			Not applicable			
Adhesion to seeds (KCP 2.10.1)	CIPAC MT 194	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	Retention capacity on treated seeds:  Peas: 98 % of metalaxyl-M 98 % of cymoxanil 98 % of fludioxonil	N	████████, 2012  <i>A9873C_10219</i>  <i>VV-400779</i>	Acceptable
Distribution to seed (KCP 2.10.2)	CIPAC MT 175	cymoxanil 98.8 g/kg fludioxonil 48.3 g/kg metalaxyl-M 170 g/kg A9873C WG	Peas: Thousand grain weight: 302.3 g  <i>metalaxyl-M</i> Minimum value: 57.4 µg/seed Maximum value: 108 µg/seed Average absorption value: 82.8 µg/seed Standard deviation: 8.83 Relative standard deviation: 10.7 %  <i>cymoxanil</i> Minimum value: 40.6 µg/seed Maximum value: 65.6 µg/seed Average absorption value: 50.9 µg/seed Standard deviation: 5.16 Relative standard deviation: 10.1 %  <i>fludioxonil</i>	N	████████, 2012  <i>A9873C_10218</i>  <i>VV-400777</i>	Acceptable  Metalaxyl-M, target loading = 105.8 µg/seed. Therefore, seed loading is 78.2 % of the target dose, which is acceptable.  <b>This data is required post storage. In this instance it would be appropriate to authorise the product under ISA – 2 year storage data on the distribution to the seed would be</b>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Minimum value: 20.7 µg/seed Maximum value: 32.4 µg/seed Average absorption value: 26.4 µg/seed Standard deviation: 2.33 Relative standard deviation: 8.83 %			<b>required for full standard authorisation. This information should be provided if the product is to placed on the market in future.</b>
Other/special studies (KCP 2.11)			Not applicable			

### 3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

## 4 Section 4: Further information on the plant protection product

### 4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	<p>It is noted that the product is not to be authorised or placed on the market as a result of this evaluation; nevertheless, packaging details are provided below.</p> <p>The proposed packaging is 1 to 10 kg HDPE and 50 kg LDPE. The applicant has provided sufficient details on the proposed packaging.</p> <p>An ambient shelf-life study has been submitted, conducted using product stored in HDPE, propylene, box with inner bag (paper/PE/PVDC), box with inner bag (paper/PE/Al), bag made of PE.</p> <p><b>Conclusion:</b></p> <p>The data indicate that a shelf life of at least 2 years at ambient temperature when stored in HDPE is supported. This can be extrapolated to support LDPE.</p>

**Table 4.1-1: Packaging information for 1 kg Canister**

Type	Description
Material:	High density polyethylene (HDPE)
Shape/size:	Canister / 158 mm x 90 mm x 244 mm (Length x Width x Height)
Opening , closure and seal:	Screw cap closure (63 mm diameter) with compression wad and tamper evident ring.
Manner of construction	Blow-molded
UN/ADR	compliant

**Table 4.1-2: Packaging information for 5 kg Canister**

Type	Description
Material:	High density polyethylene (HDPE)
Shape/size:	Canister / 237 mm x 233 mm x 307 mm (Length x Width x Height)
Opening , closure and seal:	Screw cap closure (85 mm diameter) with compression wad and tamper evident ring
Manner of construction	Blow-molded
UN/ADR	compliant

**Table 4.1-3: Packaging information for 10 kg Canister**

Type	Description
Material:	High density polyethylene (HDPE)

Type	Description
Shape/size:	Canister / 239 mm x 235 mm x 491 mm (Length x Width x Height)
Opening , closure and seal:	Screw cap closure (85 mm diameter) with compression wad and tamper evident ring
Manner of construction	Blow-molded
UN/ADR	compliant

**Table 4.1-4: Packaging information for 50 kg Bag**

Type	Description
Material:	Low density polyethylene (LDPE)
Shape/size:	Bag / 1500 mm x 810 mm (Length x Width)
Opening , closure and seal:	Closed with a plastic binding strap
Manner of construction	Blow-molded
UN/ADR	compliant

**Table 4.1-5: Packaging information for 300 kg Flexible Intermediate Bulk Container (FIBC)**

Type	Description
Material:	Liner: Polyethylene film Frame: Polypropylene woven fabric
Shape/size:	FIBC / 910 mm x 910 mm x 1150 mm (Length x Width x Height)
Opening , closure and seal:	Top: Fill spout 450mm x 600mm, closed by tie Bottom: Discharge spout 550mm x 1200mm, double closed by ties
Manner of construction	Blow-molded
UN/ADR	compliant

The packaging for the product A9873C is in compliance with all relevant UN and ADR requirements.

Stability of the packaging material has been tested during the storage stability study done according to GIFAP monograph 17.

No significant adverse effects of the product to the stability of the packaging material have been noticed.

It is concluded the packaging material will be fully resistant to the product A9873C for up to 2 years under normal storage conditions.

The initial storage stability studies determined Metalaxyl-M as a combination of the R and S enantiomers and established that the formulation was stable for 2 years at 20°C when stored in different package types. The supplementary studies carried out on HDPE used a chiral column and determined the levels of R and S enantiomers separately and demonstrated that the enantiomers are stable under storage for 2 years.

It is not known if the storage stability study on polypropylene, included a PE lining. However, the material in contact with the formulated product in both the 50kg sack and the 300KG FIBC container is polyethylene. Therefore it is considered that combination of all studies carried out supports the proposed packaging for formulation A9873C.

For details please see Appendix 3 – 8.

## Appendix 1 Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP Section 2	██████	02/12/2011	A9873C - Chemical characterization of batch KWL0K111 Report No. 123798 Document No. VV-400774 , A9873C_10212 Test Facility Syngenta Crop Protection GLP Unpublished	N	SYN
KCP 2.1	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	SYN
KCP 2.2	██████	19/01/2012	A9873C - Safety Study Report No. HT11/603 Document No. VV-400776 , A9873C_10215 Test Facility Syngenta Technology & Projects GLP Unpublished	N	SYN
KCP 2.3	██████	19/01/2012	A9873C - Safety Study Report No. HT11/603 Document No. VV-400776 , A9873C_10215 Test Facility Syngenta Technology & Projects GLP Unpublished	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.4	██████	12/01/2012	A9873C - Physical properties of batch KWL0K111 Report No. 123831 Document No. VV-400775 , A9873C_10214 Test Facility Syngenta Crop Protection GLP Unpublished	N	SYN
KCP 2.6	██████	12/01/2012	A9873C - Physical properties of batch KWL0K111 Report No. 123831 Document No. VV-400775 , A9873C_10214 Test Facility Syngenta Crop Protection GLP Unpublished	N	SYN
KCP 2.7	██████ █	03/10/2013	Ref1 A9873C - StoSta and shelf life (2we 54°C) - HDPE Report No. Document No. VV-406461 , A9873C_10311   A9873C_10217 Test Facility Ciba-Geigy Not GLP Unpublished	N	SYN
KCP 2.7	██████	12/06/2014	A9873C - Storage stability and shelf life statement (2 years 20 °C) in packaging made of HDPE Report No. 300021780 Document No. VV-407964 , A9873C_10337 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	SYN
KCP 2.7	██████	24/06/1999	Report on product stability (18 weeks 30°C, bag made of polyethylene) Report No. 14546945 Document No. VV-117175 , CGA173506/4997 Test Facility Novartis Crop Protection Münchwilen AG Not GLP Unpublished	N	ETL_blank

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.7	██████	26/01/1999	Report on product stability (18 weeks 30°C, polypropylene container) Report No. 14547068 Document No. VV-111577 , CGA173506/1310 Test Facility Novartis Crop Protection Münchwilen AG GLP Unpublished	N	ETL_blank
KCP 2.7	██████	19/09/2000	Report on product stability (2 years 20°C, bag made of polyethylene) Report No. 34686321 Document No. VV-285268 , CGA173506/5251 Test Facility Novartis Crop Protection Münchwilen AG Not GLP Unpublished	N	ETL_blank
KCP 2.7	██████	19/09/2000	Report on product stability (2 years 20°C, polypropylene container) Report No. 34689467 Document No. VV-285269 , CGA173506/5254 Test Facility Novartis Crop Protection Münchwilen AG Not GLP Unpublished	N	ETL_blank
KCP 2.8.1	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	SYN
KCP 2.8.2	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	SYN



Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.8.3	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	SYN
KCP 2.8.5.1	██████	12/01/2012	A9873C - Physical properties of batch KWL0K111 Report No. 123831 Document No. VV-400775 , A9873C_10214 Test Facility Syngenta Crop Protection GLP Unpublished	N	SYN
KCP 2.8.5.1	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	SYN
KCP 2.8.5.2	██████	12/01/2012	A9873C - Physical properties of batch KWL0K111 Report No. 123831 Document No. VV-400775 , A9873C_10214 Test Facility Syngenta Crop Protection GLP Unpublished	N	SYN
KCP 2.8.5.3	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.8.7	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	SYN
KCP 2.10	██████	09/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. SMN10736 Document No. VV-400777 , A9873C_10218 Test Facility Syngenta Biosciences Pvt. Ltd. Not GLP Unpublished	N	SYN
KCP 2.10	██████	06/01/2012	A9873C - Technical properties of batch KWL0K111 Report No. 124080 Document No. VV-400779 , A9873C_10219 Test Facility Syngenta Crop Protection Not GLP Unpublished	N	SYN

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source	Y/N	Owner

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title</b> <b>Company Report No.</b> <b>Source (where different from company)</b> <b>GLP or GEP status</b> <b>Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			GLP/non GLP/GEP/non GEP Published/Unpublished		

The following tables are to be completed by MS.

**List of data submitted by the applicant and not relied on**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

## **Appendix 2    Additional data on the physical, chemical and technical properties of the active substance**

No additional data have been generated on the active substances cymoxanil, fludioxonil and metalaxyl-M.

### Appendix 3 Storage stability data before and after storage for two weeks at 54°C in HDPE packaging

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
<b>Name of authority</b>	<b>HSE Chemicals Regulation Division (CRD), UK</b>
<b>Reviewer's comments</b>	<p>Unchanged from previous 2019 UK assessment of Storage Stability data for Wakil XL:</p> <p>Two-year storage stability data for Wakil XL have been submitted. Under the data requirements set under 2012 following zonal application: full details of the study methods and results for ██████████ (1999) CGA173506/1184, suspensibility, spontaneity of dispersion and attrition data were required for ISA to SA conversion. All submitted data has been placed in this copy of the original dRR, with newly submitted data being highlighted in turquoise.</p> <p>The application was originally a zonal assessment with reference to the product recently assessed in France to Uniform Principles, with similar GAP, formulation and label recommendations. The FR assessment was completed on 23/09/2014 with this following zonal application accepted at sift on 01/10/2014.</p> <p>Wakil XL is a water dispersible granule (WG) formulation containing three actives; 100g / kg cymoxanil, 50 g / kg fludioxonil and 175 g / kg metalaxyl-M. Wakil XL for professional use fungicidal seed treatment in peas (vining &amp; combining).</p> <p>Data requirements used in the assessment:                      The new data requirements [Regulation (EC) No. 284/2013 in accordance with Regulation (EC) 1107/2009] will apply to this product assessment.</p> <p><b>Distribution to seed</b></p> <p>Full details of the study methods and results for ██████████ (1999) CGA173506/1184 have been submitted. However, the %RSD is 36 % is outside the set limit. The uniformity of distribution to seed raw data (██████████) has subsequently been submitted at W001843165. It is noted that the %RSD is 36 % which greater than the 25 % limit. However, MT 175 is a method developed for liquid seed treatments rather than WG and is predominantly directed towards cereals rather than pea seed treatments. Additionally, the product has been on the market for a number of years and no issues with efficacy have been reported, therefore distribution to seed is acceptable.</p> <p><b>Suspensibility</b></p> <p>Suspensibility results are for 10 and 60 % w/v concentrations where the in use concentration is 40 % w/v. Physical Chemistry Guidance states that the highest and lowest in use concentrations should be tested, however, given that the range tested encompasses the label in use concentration (40 % w/v) this is acceptable. Results are within the 60 - 105 % active suspensibility range and are acceptable.</p> <p><b>Spontaneity of dispersion</b></p> <p>Data was gravimetrically determined which is unacceptable. For a product with multiple actives, <i>Physical Chemistry Guidance</i> requires that each of the A.S must be determined via chemical assay. However, the label instructs to apply “continue[d] agitation during use”, which would keep the granules homogeneously distributed in solution, negating the need for</p>

	chemical assay testing. In this case the data is considered overall acceptable.
	<b>Attrition</b>  Attrition data was not submitted for a stored 300 kg bag. A 2 year storage attrition test was conducted using a sample from an undisclosed HDPE pack size – which was later confirmed to be 1 L. In accordance with The <i>Physical Chemistry Guidance</i> “Where it is proposed that a preparation is to be packaged in a bulk container (a container of size greater than 20 L), it is recognised that it is impractical to conduct stability tests in the large containers. Therefore, results from smaller volume containers (1 l upwards) may be used to extrapolate to the larger containers”.

**Table A3-1: Content of active substances before and after storage for two weeks at 54°C in HDPE packaging**

Active Substance	Initial	2 weeks below - 10°C(control sample)	2 weeks 54°C (test sample)
Metalaxyl-M	17.0% w/w	17.0% w/w	16.9% w/w
Cymoxanil	9.88% w/w	9.86% w/w	9.39% w/w
Fludioxonil	4.83% w/w	4.83% w/w	4.84% w/w

**Table A3-2: Physical and technical properties before and after storage for two weeks at 54°C in HDPE packaging**

Test Description	Method	Initial Results	Results after 2 weeks at 54°C
<b>Color</b>	Visual	Red	Red
<b>Odor</b>	Organoleptic	Weak	Weak
<b>Physical State</b>	Visual	Solid	Solid
<b>Appearance</b>	Visual	-	Free flowing, no compaction, granule integrity unchanged
<b>pH Value</b> Concentration: 1% Deionized Water	CIPAC MT 75.3	6.0	6.0
<b>Dust content</b>	CIPAC MT 171	0.4 mg	0.4 mg
<b>Wettability</b> CIPAC Water D	CIPAC MT 53.3	7 sec	7 sec
<b>Wet Sieve</b> sieve size: 75 µm	CIPAC MT 185	< 0.01%	< 0.01%
<b>Persistent foaming</b> in CIPAC water D at room temperature Concentration : 60 % w/v Concentration : 10 % w/v	CIPAC MT 47.2	0 mL 0 mL	0 mL 0 mL

Test Description	Method	Initial Results	Results after 2 weeks at 54°C
<b>Suspensibility</b> in CIPAC water D after 30 minutes. Temperature : 30°C ± 2°C Concentration : 60 % Metalaxyl-M Cymoxanil Fludioxonil	CIPAC MT 184 (chemical assay)	100 % 100 % 100 %	100 % 100 % 100 %
<b>Suspensibility</b> in CIPAC water D after 30 minutes. Temperature : 30°C ± 2°C Concentration : 10 % Metalaxyl-M Cymoxanil Fludioxonil	CIPAC MT 184 (chemical assay)	94 % 67 % 87 %	95 % 69 % 89 %
<b>Spontaneity of dispersion</b> in CIPAC water D at 20°C	CIPAC MT 174 (gravimetrically)	96 %	96 %
<b>Friability and attrition resistance</b>	CIPAC MT 178.2	100%	100%
<b>Adhesion to Seeds (Pea)</b> Retention capacity metalaxyl-M cymoxanil fludioxonil	CIPAC MT 194	98% 98% 98%	95% 95% 96%

**Table A3-3: Packaging Evaluation after storage for two weeks at 54°C in HDPE packaging**

Evaluation Criteria	Results after 2 weeks at 54°C
Color change of the packaging	None
Odor (noticeable before opening the packaging)	None
Panelling of the test container	None
Ballooning of the test container	None
Pimples on the test container	None
Cracks in the test container	None
Tightness of the test container	Tight
Reclosability of closure	Reclosable
Tightness of closure	Tight
Weight change (gross weight)	0.02% weight loss



## Appendix 4 Storage stability data before and after storage for 18 weeks at 30 °C in Polypropylene packaging

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
<b>Name of authority</b>	<b>HSE Chemicals Regulation Division (CRD), UK</b>
<b>Reviewer's comments</b>	<p>Two-year storage stability data for Wakil XL have been submitted. Under the data requirements set under 2012 following zonal application: full details of the study methods and results for [REDACTED] (1999) CGA173506/1184, suspensibility, spontaneity of dispersion and attrition data were required for ISA to SA conversion. All submitted data has been placed in this copy of the original dRR, with newly submitted data being highlighted in turquoise.</p> <p>The application was originally a zonal assessment with reference to the product recently assessed in France to Uniform Principles, with similar GAP, formulation and label recommendations. The FR assessment was completed on 23/09/2014 with this following zonal application accepted at sift on 01/10/2014.</p> <p>Wakil XL is a water dispersible granule (WG) formulation containing three actives; 100g / kg cymoxanil, 50 g / kg fludioxonil and 175 g / kg metalaxyl-M. Wakil XL for professional use fungicidal seed treatment in peas (vining &amp; combining).</p> <p>Data requirements used in the assessment:  The new data requirements [Regulation (EC) No. 284/2013 in accordance with Regulation (EC) 1107/2009] will apply to this product assessment.</p> <p><b>Distribution to seed</b></p> <p>Full details of the study methods and results for [REDACTED] (1999) CGA173506/1184 have been submitted. However, the %RSD is 36 % is outside the set limit. The uniformity of distribution to seed raw data ([REDACTED]) has subsequently been submitted at W001843165. It is noted that the %RSD is 36 % which greater than the 25 % limit. However, MT 175 is a method developed for liquid seed treatments rather than WG and is predominantly directed towards cereals rather than pea seed treatments. Additionally, the product has been on the market for a number of years and no issues with efficacy have been reported, therefore distribution to seed is acceptable.</p> <p><b>Suspensibility</b></p> <p>Suspensibility results are for 10 and 60 % w/v concentrations where the in use concentration is 40 % w/v. Physical Chemistry Guidance states that the highest and lowest in use concentrations should be tested, however, given that the range tested encompasses the label in use concentration (40 % w/v) this is acceptable. Results are within the 60 - 105 % active suspensibility range and are acceptable.</p> <p><b>Spontaneity of dispersion</b></p> <p>Data was gravimetrically determined which is unacceptable. For a product with multiple actives, <i>Physical Chemistry Guidance</i> requires that each of the A.S must be determined via chemical assay. However, the label instructs to apply “continue[d] agitation during use”, which would keep the granules homogeneously distributed in solution, negating the need for chemical assay testing. In this case the data is considered overall acceptable.</p>

<b>Attrition</b>	<p>Attrition data was not submitted for a stored 300 kg bag. A 2 year storage attrition test was conducted using a sample from an undisclosed HDPE pack size – which was later confirmed to be 1 L. In accordance with The <i>Physical Chemistry Guidance</i> “Where it is proposed that a preparation is to be packaged in a bulk container (a container of size greater than 20 L), it is recognised that it is impractical to conduct stability tests in the large containers. Therefore, results from smaller volume containers (1 l upwards) may be used to extrapolate to the larger containers”.</p>
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**Table A4-1: Content of active substances before and after storage for 18 weeks at 30°C in Polypropylene packaging**

Active Substance	Initial	18 weeks below - 10°C(control sample)	18 weeks at 30 °C (test sample)
Metalaxyl-M (including the S-enantiomer)	17.9 %	17.5 %	17.6 %
Cymoxanil	10.4 %	10.5 %	10.4 %
Fludioxonil	4.86 %	4.97 %	4.93 %

**Table A4-2: Physical and technical properties before and after storage for two years at 20°C in Polypropylene packaging**

Test Description	Method	Initial Results	Results after 18 weeks at 30°C
<b>Color</b>	Visual	Red	Red
<b>Odor</b>	Organoleptic	Weak	Weak
<b>Physical State</b>	Visual	Solid	Solid
<b>Appearance</b>	Visual	-	Free flowing, no compaction, granule integrity unchanged
<b>pH Value</b> Concentration: 1% Deionized Water	CIPAC MT 75.3	6.0	6.1
<b>Wettability</b> in CIPAC water C	CIPAC MT 53.3	3 s	2 s
<b>Dust content</b>	CIPAC MT 171	0.4 mg	0.6 mg
<b>Wet Sieve</b> sieve size: 75 µm	CIPAC MT 185	0.05 %	0.02 %
<b>Spontaneity of dispersion</b> in CIPAC water D at 20°C	CIPAC MT 174 (gravimetrically)	98%	98%

**Table A4-3: Packaging Evaluation after storage for 18 weeks at 30°C in Polypropylene packaging**

Evaluation Criteria	Results after 2 years 20°C
Color change of the packaging	None
Odor (noticeable before opening the packaging)	None
Panelling of the test container	None

Ballooning of the test container	None
Pimples on the test container	None
Cracks in the test container	None
Tightness of the test container	Tight
Reclosability of closure	Reclosable
Tightness of closure	Tight
Weight change (gross weight)	0.39% weight loss

## Appendix 5 Storage stability data before and after storage for 18 weeks at 30 °C in Polyethylene packaging

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
<b>Name of authority</b>	<b>HSE Chemicals Regulation Division (CRD), UK</b>
<b>Reviewer's comments</b>	<p>Two-year storage stability data for Wakil XL have been submitted. Under the data requirements set under 2012 following zonal application: full details of the study methods and results for [REDACTED] (1999) CGA173506/1184, suspensibility, spontaneity of dispersion and attrition data were required for ISA to SA conversion. All submitted data has been placed in this copy of the original dRR, with newly submitted data being highlighted in turquoise.</p> <p>The application was originally a zonal assessment with reference to the product recently assessed in France to Uniform Principles, with similar GAP, formulation and label recommendations. The FR assessment was completed on 23/09/2014 with this following zonal application accepted at sift on 01/10/2014.</p> <p>Wakil XL is a water dispersible granule (WG) formulation containing three actives; 100g / kg cymoxanil, 50 g / kg fludioxonil and 175 g / kg metalaxyl-M. Wakil XL for professional use fungicidal seed treatment in peas (vining &amp; combining).</p> <p>Data requirements used in the assessment:  The new data requirements [Regulation (EC) No. 284/2013 in accordance with Regulation (EC) 1107/2009] will apply to this product assessment.</p> <p><b>Distribution to seed</b></p> <p>Full details of the study methods and results for [REDACTED] (1999) CGA173506/1184 have been submitted. However, the %RSD is 36 % is outside the set limit. The uniformity of distribution to seed raw data ([REDACTED]) has subsequently been submitted at W001843165. It is noted that the %RSD is 36 % which greater than the 25 % limit. However, MT 175 is a method developed for liquid seed treatments rather than WG and is predominantly directed towards cereals rather than pea seed treatments. Additionally, the product has been on the market for a number of years and no issues with efficacy have been reported, therefore distribution to seed is acceptable.</p> <p><b>Suspensibility</b></p> <p>Suspensibility results are for 10 and 60 % w/v concentrations where the in use concentration is 40 % w/v. Physical Chemistry Guidance states that the highest and lowest in use concentrations should be tested, however, given that the range tested encompasses the label in use concentration (40 % w/v) this is acceptable. Results are within the 60 - 105 % active suspensibility range and are acceptable.</p> <p><b>Spontaneity of dispersion</b></p> <p>Data was gravimetrically determined which is unacceptable. For a product with multiple actives, <i>Physical Chemistry Guidance</i> requires that each of the A.S must be determined via chemical assay. However, the label instructs to apply “continue[d] agitation during use”, which would keep the granules homogeneously distributed in solution, negating the need for chemical assay testing. In this case the data is considered overall acceptable.</p>

	<p><b>Attrition</b></p> <p>Attrition data was not submitted for a stored 300 kg bag. A 2 year storage attrition test was conducted using a sample from an undisclosed HDPE pack size – which was later confirmed to be 1 L. In accordance with The <i>Physical Chemistry Guidance</i> “Where it is proposed that a preparation is to be packaged in a bulk container (a container of size greater than 20 L), it is recognised that it is impractical to conduct stability tests in the large containers. Therefore, results from smaller volume containers (1 l upwards) may be used to extrapolate to the larger containers”.</p>
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**Table A5-1: Content of active substances before and after storage for 18 weeks at 30°C in Polyethylene packaging**

Active Substance	Initial	18 weeks below - 10°C(control sample)	18 weeks at 30 °C (test sample)
Metalaxyl-M (including the S-enantiomer)	17.9 %	17.5 %	17.6 %
Cymoxanil	10.4 %	10.5 %	10.4 %
Fludioxonil	4.86 %	4.97 %	4.84 %

**Table A5-2: Physical and technical properties before and after storage for two years at 20°C in Polyethylene packaging**

Test Description	Method	Initial Results	Results after 18 weeks at 30°C
<b>Color</b>	Visual	Red	Red
<b>Odor</b>	Organoleptic	Weak	Weak
<b>Physical State</b>	Visual	Solid	Solid
<b>Appearance</b>	Visual	-	Free flowing, no compaction, granule integrity unchanged
<b>pH Value</b> Concentration: 1% Deionized Water	CIPAC MT 75.3	5.9	6.1
<b>Wettability</b> in CIPAC water C	CIPAC MT 53.3	4 s	3 s
<b>Dust content</b>	CIPAC MT 171	0.2 mg	0.4 mg
<b>Wet Sieve</b> sieve size: 75 µm	CIPAC MT 185	0.05 %	0.02%
<b>Spontaneity of dispersion</b> in CIPAC water D at 20°C	CIPAC MT 174 (gravimetrically)	98%	96%

**Table A5-3: Packaging Evaluation after storage for 18 weeks at 30°C in Polyethylene packaging**

Evaluation Criteria	Results after 18 weeks at 30°C
Color change of the packaging	None
Odor (noticeable before opening the packaging)	None
Ballooning of the test container	None

Pimples on the test container	None, slightly sticky
Tightness of the test container	Tight
Weight change (gross weight)	2.13 % weight loss

## Appendix 6 Storage stability data before and after storage for two years at 20°C in Polypropylene packaging

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
<b>Name of authority</b>	<b>HSE Chemicals Regulation Division (CRD), UK</b>
<b>Reviewer's comments</b>	<p>Two-year storage stability data for Wakil XL have been submitted. Under the data requirements set under 2012 following zonal application: full details of the study methods and results for [REDACTED] (1999) CGA173506/1184, suspensibility, spontaneity of dispersion and attrition data were required for ISA to SA conversion. All submitted data has been placed in this copy of the original dRR, with newly submitted data being highlighted in turquoise.</p> <p>The application was originally a zonal assessment with reference to the product recently assessed in France to Uniform Principles, with similar GAP, formulation and label recommendations. The FR assessment was completed on 23/09/2014 with this following zonal application accepted at sift on 01/10/2014.</p> <p>Wakil XL is a water dispersible granule (WG) formulation containing three actives; 100g / kg cymoxanil, 50 g / kg fludioxonil and 175 g / kg metalaxyl-M. Wakil XL for professional use fungicidal seed treatment in peas (vining &amp; combining).</p> <p>Data requirements used in the assessment:  The new data requirements [Regulation (EC) No. 284/2013 in accordance with Regulation (EC) 1107/2009] will apply to this product assessment.</p> <p><b>Distribution to seed</b></p> <p>Full details of the study methods and results for [REDACTED] (1999) CGA173506/1184 have been submitted. However, the %RSD is 36 % is outside the set limit. The uniformity of distribution to seed raw data ([REDACTED]) has subsequently been submitted at W001843165. It is noted that the %RSD is 36 % which greater than the 25 % limit. However, MT 175 is a method developed for liquid seed treatments rather than WG and is predominantly directed towards cereals rather than pea seed treatments. Additionally, the product has been on the market for a number of years and no issues with efficacy have been reported, therefore distribution to seed is acceptable.</p> <p><b>Suspensibility</b></p> <p>Suspensibility results are for 10 and 60 % w/v concentrations where the in use concentration is 40 % w/v. Physical Chemistry Guidance states that the highest and lowest in use concentrations should be tested, however, given that the range tested encompasses the label in use concentration (40 % w/v) this is acceptable. Results are within the 60 - 105 % active suspensibility range and are acceptable.</p> <p><b>Spontaneity of dispersion</b></p> <p>Data was gravimetrically determined which is unacceptable. For a product with multiple actives, <i>Physical Chemistry Guidance</i> requires that each of the A.S must be determined via chemical assay. However, the label instructs to apply “continue[d] agitation during use”, which would keep the granules homogeneously distributed in solution, negating the need for chemical assay testing. In this case the data is considered overall acceptable.</p>

	<b>Attrition</b>  Attrition data was not submitted for a stored 300 kg bag. A 2 year storage attrition test was conducted using a sample from an undisclosed HDPE pack size – which was later confirmed to be 1 L. In accordance with The <i>Physical Chemistry Guidance</i> “Where it is proposed that a preparation is to be packaged in a bulk container (a container of size greater than 20 L), it is recognised that it is impractical to conduct stability tests in the large containers. Therefore, results from smaller volume containers (1 l upwards) may be used to extrapolate to the larger containers”.
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**Table A6-1: Content of active substances before and after storage for two years at 20°C in Polypropylene packaging**

Active Substance	Initial	2 weeks below - 10°C(control sample)	2 years 20 °C (test sample)
Metalaxyl-M (including the S-enantiomer)	17.9 %	17.4 %	17.6 %
Cymoxanil	10.4 %	10.5 %	10.4 %
Fludioxonil	4.86 %	4.89 %	4.93 %

**Table A6-2: Physical and technical properties before and after storage for two years at 20°C in Polypropylene packaging**

Test Description	Method	Initial Results	Results after 2 years at 20°C
<b>Color</b>	Visual	Red	Red
<b>Odor</b>	Organoleptic	Weak	Weak
<b>Physical State</b>	Visual	Solid	Solid
<b>Appearance</b>	Visual	-	Free flowing, no compaction, granule integrity unchanged
<b>pH Value</b> Concentration: 1% Deionized Water	CIPAC MT 75.3	5.9	6.1
<b>Wettability</b> in CIPAC water C	CIPAC MT 53.3	3 s	2 s
<b>Dust content</b>	CIPAC MT 171	0.2 mg	0.6 mg
<b>Wet Sieve</b> sieve size: 75 µm	CIPAC MT 185	0.05 %	0.02%
<b>Spontaneity of dispersion</b> in CIPAC water D at 20°C	CIPAC MT 174 (gravimetrically)	98%	98%

**Table A6-3: Packaging Evaluation after storage for two years at 20°C in Polypropylene packaging**

Evaluation Criteria	Results after 2 years 20°C
Color change of the packaging	None
Odor (noticeable before opening the packaging)	None
Paneling of the test container	None



Ballooning of the test container	None
Pimples on the test container	None
Cracks in the test container	None
Tightness of the test container	Tight
Reclosability of closure	Reclosable
Tightness of closure	Tight
Weight change (gross weight)	0.39% weight loss

## Appendix 7 Storage stability data before and after storage for two years at 20°C in Polyethylene packaging

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
<b>Name of authority</b>	<b>HSE Chemicals Regulation Division (CRD), UK</b>
<b>Reviewer's comments</b>	<p>Two-year storage stability data for Wakil XL have been submitted. Under the data requirements set under 2012 following zonal application: full details of the study methods and results for [REDACTED] (1999) CGA173506/1184, suspensibility, spontaneity of dispersion and attrition data were required for ISA to SA conversion. All submitted data has been placed in this copy of the original dRR, with newly submitted data being highlighted in turquoise.</p> <p>The application was originally a zonal assessment with reference to the product recently assessed in France to Uniform Principles, with similar GAP, formulation and label recommendations. The FR assessment was completed on 23/09/2014 with this following zonal application accepted at sift on 01/10/2014.</p> <p>Wakil XL is a water dispersible granule (WG) formulation containing three actives; 100g / kg cymoxanil, 50 g / kg fludioxonil and 175 g / kg metalaxyl-M. Wakil XL for professional use fungicidal seed treatment in peas (vining &amp; combining).</p> <p>Data requirements used in the assessment:  The new data requirements [Regulation (EC) No. 284/2013 in accordance with Regulation (EC) 1107/2009] will apply to this product assessment.</p> <p><b>Distribution to seed</b></p> <p>Full details of the study methods and results for [REDACTED] (1999) CGA173506/1184 have been submitted. However, the %RSD is 36 % is outside the set limit. The uniformity of distribution to seed raw data ([REDACTED]) has subsequently been submitted at W001843165. It is noted that the %RSD is 36 % which greater than the 25 % limit. However, MT 175 is a method developed for liquid seed treatments rather than WG and is predominantly directed towards cereals rather than pea seed treatments. Additionally, the product has been on the market for a number of years and no issues with efficacy have been reported, therefore distribution to seed is acceptable.</p> <p><b>Suspensibility</b></p> <p>Suspensibility results are for 10 and 60 % w/v concentrations where the in use concentration is 40 % w/v. Physical Chemistry Guidance states that the highest and lowest in use concentrations should be tested, however, given that the range tested encompasses the label in use concentration (40 % w/v) this is acceptable. Results are within the 60 - 105 % active suspensibility range and are acceptable.</p> <p><b>Spontaneity of dispersion</b></p> <p>Data was gravimetrically determined which is unacceptable. For a product with multiple actives, <i>Physical Chemistry Guidance</i> requires that each of the A.S must be determined via chemical assay. However, the label instructs to apply “continue[d] agitation during use”, which would keep the granules homogeneously distributed in solution, negating the need for chemical assay testing. In this case the data is considered overall acceptable.</p>

	<b>Attrition</b>  Attrition data was not submitted for a stored 300 kg bag. A 2 year storage attrition test was conducted using a sample from an undisclosed HDPE pack size – which was later confirmed to be 1 L. In accordance with The <i>Physical Chemistry Guidance</i> “Where it is proposed that a preparation is to be packaged in a bulk container (a container of size greater than 20 L), it is recognised that it is impractical to conduct stability tests in the large containers. Therefore, results from smaller volume containers (1 l upwards) may be used to extrapolate to the larger containers”.
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**Table A7-1: Content of active substances before and after storage for two years at 20°C in Polyethylene packaging**

Active Substance	Initial	2 weeks below - 10°C(control sample)	2 years 20 °C (test sample)
Metalaxyl-M (including the S-enantiomer)	17.9 %	17.6 %	17.8 %
Cymoxanil	10.4 %	10.2 %	10.2 %
Fludioxonil	4.86 %	4.8 %	4.76 %

**Table A7-2: Physical and technical properties before and after storage for two years at 20°C in Polyethylene packaging**

Test Description	Method	Initial Results	Results after 2 years at 20°C
<b>Color</b>	Visual	Red	Red
<b>Odor</b>	Organoleptic	Weak	Weak
<b>Physical State</b>	Visual	Solid	Solid
<b>Appearance</b>	Visual	-	Free flowing, no compaction, granule integrity unchanged
<b>pH Value</b> Concentration: 1% Deionized Water	CIPAC MT 75.3	5.9	6.1
<b>Wettability</b> in CIPAC water C	CIPAC MT 53.3	3 s	3 s
<b>Dust content</b>	CIPAC MT 171	0.2 mg	0.1 mg
<b>Wet Sieve</b> sieve size: 75 µm	CIPAC MT 185	0.05 %	0.04%
<b>Spontaneity of dispersion</b> in CIPAC water D at 20°C	CIPAC MT 174 (gravimetrically)	98%	96%

**Table A7-3: Packaging Evaluation after storage for two years at 20°C in Polyethylene packaging**

Evaluation Criteria	Results after 2 years 20°C
Color change of the packaging	None
Odor (noticeable before opening the packaging)	None
Ballooning of the test container	None

Pimples on the test container	None
Tightness of the test container	Tight
Weight change (gross weight)	1.16 % weight loss

## Appendix 8 Storage stability data before and after storage for two years at 20°C in HDPE packaging

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
<b>Name of authority</b>	<b>HSE Chemicals Regulation Division (CRD), UK</b>
<b>Reviewer's comments</b>	<p>Two-year storage stability data for Wakil XL have been submitted. Under the data requirements set under 2012 following zonal application: full details of the study methods and results for [REDACTED] (1999) CGA173506/1184, suspensibility, spontaneity of dispersion and attrition data were required for ISA to SA conversion. All submitted data has been placed in this copy of the original dRR, with newly submitted data being highlighted in turquoise.</p> <p>The application was originally a zonal assessment with reference to the product recently assessed in France to Uniform Principles, with similar GAP, formulation and label recommendations. The FR assessment was completed on 23/09/2014 with this following zonal application accepted at sift on 01/10/2014.</p> <p>Wakil XL is a water dispersible granule (WG) formulation containing three actives; 100g / kg cymoxanil, 50 g / kg fludioxonil and 175 g / kg metalaxyl-M. Wakil XL for professional use fungicidal seed treatment in peas (vining &amp; combining).</p> <p>Data requirements used in the assessment:  The new data requirements [Regulation (EC) No. 284/2013 in accordance with Regulation (EC) 1107/2009] will apply to this product assessment.</p> <p><b>Distribution to seed</b></p> <p>Full details of the study methods and results for [REDACTED] (1999) CGA173506/1184 have been submitted. However, the %RSD is 36 % is outside the set limit. The uniformity of distribution to seed raw data ([REDACTED]) has subsequently been submitted at W001843165. It is noted that the %RSD is 36 % which greater than the 25 % limit. However, MT 175 is a method developed for liquid seed treatments rather than WG and is predominantly directed towards cereals rather than pea seed treatments. Additionally, the product has been on the market for a number of years and no issues with efficacy have been reported, therefore distribution to seed is acceptable.</p> <p><b>Suspensibility</b></p> <p>Suspensibility results are for 10 and 60 % w/v concentrations where the in use concentration is 40 % w/v. Physical Chemistry Guidance states that the highest and lowest in use concentrations should be tested, however, given that the range tested encompasses the label in use concentration (40 % w/v) this is acceptable. Results are within the 60 - 105 % active suspensibility range and are acceptable.</p> <p><b>Spontaneity of dispersion</b></p> <p>Data was gravimetrically determined which is unacceptable. For a product with multiple actives, <i>Physical Chemistry Guidance</i> requires that each of the A.S must be determined via chemical assay. However, the label instructs to apply “continue[d] agitation during use”, which would keep the granules homogeneously distributed in solution, negating the need for chemical assay testing. In this case the data is considered overall acceptable.</p>

	<p><b>Attrition</b></p> <p>Attrition data was not submitted for a stored 300 kg bag. A 2 year storage attrition test was conducted using a sample from an undisclosed HDPE pack size – which was later confirmed to be 1 L. In accordance with The <i>Physical Chemistry Guidance</i> “Where it is proposed that a preparation is to be packaged in a bulk container (a container of size greater than 20 L), it is recognised that it is impractical to conduct stability tests in the large containers. Therefore, results from smaller volume containers (1 l upwards) may be used to extrapolate to the larger containers”.</p>
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**Table A8-1: Content of active substances before and after storage for two years at 20°C in HDPE packaging**

Active Substance	Initial	2 weeks below - 10°C(control sample)	2 years 20 °C (test sample)
Metalaxyl-M	170 g/kg	173 g/kg	173 g/kg
Cymoxanil	98.8 g/kg	97.9 g/kg	96.9 g/kg
Fludioxonil	48.3 g/kg	48.2 g/kg	48.2 g/kg

**Table A8-2: Physical and technical properties before and after storage for two years at 20°C in HDPE packaging**

Test Description	Method	Initial Results	Results after 2 years at 20°C
<b>Color</b>	Visual	Red	Red
<b>Odor</b>	Organoleptic	Weak	Weak
<b>Physical State</b>	Visual	Solid	Solid
<b>Appearance</b>	Visual	-	Free flowing, no compaction, granule integrity unchanged
<b>pH Value</b> Concentration: 1% Deionized Water	CIPAC MT 75.3	6.0	6.3
<b>Dust content</b>	CIPAC MT 171	0.4 mg	0.6 mg
<b>Wet Sieve</b> sieve size: 75 µm	CIPAC MT 185	< 0.01%	0.01%
<b>Suspensibility</b> in CIPAC water D after 30 minutes. Temperature : 30°C ± 2°C Concentration : 60 % Metalaxyl-M Cymoxanil Fludioxonil	CIPAC MT 184 (chemical assay)	100% 100% 100%	97% 98% 97%
<b>Suspensibility</b> in CIPAC water D after 30 minutes. Temperature : 30°C ± 2°C Concentration : 10% Metalaxyl-M Cymoxanil Fludioxonil	CIPAC MT 184 (chemical assay)	94% 67% 87%	94% 69% 88%

Test Description	Method	Initial Results	Results after 2 years at 20°C
<b>Spontaneity of dispersion</b> in CIPAC water D at 20°C	CIPAC MT 174 (gravimetrically)	96%	96%
<b>Friability and attrition resistance</b>	CIPAC MT 178.2	100%	100%
<b>Adhesion to Seeds (Pea)</b> Retention capacity metalaxyl-M cymoxanil fludioxonil	CIPAC MT 194	98% 98% 98%	95% 96% 96%

**Table A8-3: Packaging Evaluation after storage for two years at 20°C in HDPE packaging**

Evaluation Criteria	Results after 2 years 20°C
Color change of the packaging	None
Odor (noticeable before opening the packaging)	None
Panelling of the test container	None
Ballooning of the test container	None
Pimples on the test container	None
Cracks in the test container	None
Tightness of the test container	Tight
Reclosability of closure	Reclosable
Tightness of closure	Tight
Weight change (gross weight)	0.09% weight loss