

# 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: A20607B

Product name(s): Vibrance SB

Chemical active substance(s):

Fludioxonil, 22.5 g/L

Metalaxyl-M, 14.4 g/L

Sedaxane, 15 g/L

~~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: 21/08/2021

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 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.

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>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 substance(s).

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's comments	<p><b>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 to the GB 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.</b></p> <p>This application is for the amendment to the GB 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, see above.</p> <p>The information presented below in the RR has been written by the applicant, where required, comments have been inserted in green boxes by the UK or the text amended by the UK in green (applicant's text has been struck through in green where necessary).</p> <p><b>All relied upon studies 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.</b></p> <p>'Vibrance SB' is a FS formulation containing 14.4 g/L metalaxyl-M, 15 g/L sedaxane and 22.5 g/L fludioxonil.</p> <p>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.</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>). '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 <math>550 \pm 55^{\circ}\text{C}</math>. The pH of the 1% dilution of the preparation is 6.7.</p> <p>Acceptable physical, chemical and technical data have been provided indicating that the product fulfils the requirements of a FS formulation.</p> <p>Acceptable accelerated (2 weeks at <math>54^{\circ}\text{C}</math>) 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.</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 (2020 APPLICATION FOR 'Apron XL' renewal). The applicant's 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</p>

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 ‘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.

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

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

Name: Syngenta Crop Protection AG

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Switzerland

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Syngenta Crop Protection AG  
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Switzerland

Phone: 

Fax: 

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## 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 substance(s)

Confidential information - data provided separately (Part C).

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

#### 1.2.3.1 Fludioxonil

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>	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.

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

#### Pure fludioxonil in A20607B

<b>content of pure active substance:</b>	<b>22.5 g/L</b>	<b>2.18 % w/w</b>
limits :	19.1 – 25.9 g/L	1.85 – 2.51 % w/w

#### Technical fludioxonil in A20607B

<b>at a minimum purity of the technical active substance of 95.0 % w/w.</b>		
<b>content of technical active substance:</b>	<b>23.7 g/L</b>	<b>2.29 % w/w</b>
limits :	20.1 – 27.2 g/L	1.95 – 2.63 % w/w

#### 1.2.3.2 Metalaxyl-M

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>	<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 'A20607B' complies with the conditions of approval. Please see Volume 4 for further information.</p> <p>The declared content of metalaxyl-M in 'A20607B' 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>

<b>Test Substance</b>	<b>EU agreed minimum purity Reference: IMPLEMENTING REGULATION (EU) 2020/617</b>
Metalaxyl-M	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-M in A20607B

<b>content of pure active substance:</b>	<b>14.4 g/L</b>	<b>1.40 % w/w</b>
limits :	12.2 – 16.6 g/L	1.19 – 1.60 % w/w

#### Technical metalaxyl-M in A20607B

<b>at a minimum purity of the technical active substance of 92.0% w/w.</b>		
<b>content of technical active substance:</b>	<b>15.7 g/L</b>	<b>1.52 % w/w</b>
limits :	13.3 - 18.0 g/L	1.29 – 1.74 % w/w

#### 1.2.3.3 Sedaxane

<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</b>	As this Article 7 amendment only concerns metalaxyl-M, and as the product 'Vibrance SB' is not



comments	to be approved for use – the product has only been evaluated with respect to metalaxyl-M. Fludioxonil and sedaxane have not been considered further.
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<b>Name of Substance</b>	<b>EU agreed minimum purity</b> <b>Reference: COMMISSION IMPLEMENTING REGULATION (EU) 826/2013</b>
<b>Sedaxane</b>	Min. 960 g/kg

#### Pure sedaxane in A20607B

<b>content of pure active substance:</b>	<b>15.0 g/L</b>	<b>1.45 % w/w</b>
limits :	12.7 – 17.2 g/L	1.24 – 1.67 % w/w

#### Technical sedaxane in A20607B

<b>at a minimum purity of the technical active substance of 96.0% w/w.</b>		
<b>content of technical active substance:</b>	<b>15.6 g/L</b>	<b>1.51 % w/w</b>
limits :	13.3 – 18.0 g/L	1.29 – 1.74 % 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: Please refer to Registration Report Part A for the relevant country (or)  
 Trade name: VIBRANCE SB  
 Company code number: A20607B

### 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 A20607B was not evaluated previously as a representative formulation (same uses and same GAPs) during the EU review of the active substances fludioxonil, metalaxyl-M and sedaxane.

The content of fludioxonil, metalaxyl-M and sedaxane in A20607B 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 substance(s) (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 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.	522	

**Table 1.4.2-2: 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	

**Table 1.4.2-3: Information on sedaxane**

Type	Name/Code Number	
ISO common name	Sedaxane (SYN524464)	Variant: not relevant
CAS No.	874967-67-6	
EC No.	<del>Not allocated</del> 688-331-2	
CIPAC No.	833	

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	HSE Chemicals Regulation Division (CRD), UK
Reviewer's	'A20607B' does not contain any safeners or synergists

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

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

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.

Type: Flowable concentrate for seed treatment [Code: FS]

### 1.6 Function (KCP 1.6)

Fungicide for seed treatment

## 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><b>All relied upon studies 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.</b></p> <p>‘Vibrance SB’ is a FS formulation containing 14.4 g/L metalaxyl-M, 15 g/L sedaxane and 22.5 g/L fludioxonil.</p> <p>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.</p> <p>All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable (studies previously evaluated have not been reopened). ‘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 <math>550 \pm 55^{\circ}\text{C}</math>. The pH of the 1% dilution of the preparation is 6.7.</p> <p>Acceptable physical, chemical and technical data have been provided indicating that the product fulfils the requirements of a FS formulation.</p> <p>Acceptable accelerated (2 weeks at <math>54^{\circ}\text{C}</math>) 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.</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 (‘Apron XL’ 2020 renewal). 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 ‘Vibrance SB’, this case may not be accepted for future products.</p> <p>A low temperature storage stability data is required and has been submitted.</p> <p>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.</p>

**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.

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  $550 \pm 55^\circ\text{C}$ . 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 A20607B.

**Compliance with FAO specifications:**

The product A20607B complies with FAO specifications.

**Formulation used for tests**

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

**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:

SMU4DP001 (A20607B) containing a mean of 15.6 g/L sedaxane, 23.3 g/L fludioxonil and 15.3 g/L metalaxyl-M (■■■■■ 2015, VV-412226)

SMU7AL007 (A20607B) containing a mean of 15.4 g/L sedaxane, 22.8 g/L fludioxonil and 15.1 g/L metalaxyl-M (■■■■■ 2017, VV-858601)

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual and organoleptical assesement	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	Physical state: liquid Colour: light grey Odour: mild	Y	■■■■■ 2015 (VV-412228)	Acceptable; assessed under 2018 submission to meet outstanding data requiremetns for ‘Vibrance SB’.
Explosive properties (KCP 2.2.1)	ASTM E537 (DSC method)	A20607B sedaxane 15.4 g/L, fludioxonil 22.8 g/L, metalaxyl-M 15.1 g/L batch no. SMU7AL007	The heat of decomposition of the test substance = 63 J/g. The heat of decomposition of the test substance is well below the 500 J/g threshold specified by Appendix 6 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria (Reference 5.1). Not classified as an explosive substance.	Y	■■■■■ 2017 (VV-467979)  ■■■■■ 2014 (A20607B_101 86)	Acceptable – ■■■■■ 2017 not evaluated, ■■■■■ 2014 is acceptable-assessed under 2018 submission to meet outstanding data requiremetns for ‘Vibrance SB’
Oxidizing properties (KCP 2.2.2)	Theoretical assesement (according to UN Test O.2)	A20607B sedaxane 15.4 g/L, fludioxonil 22.8 g/L, metalaxyl-M 15.1 g/L batch no. SMU7AL007	Not classified as an oxidizing substance	N	■■■■■ 2017 (VV-467979)  ■■■■■ 2014 (A20607B_101 86)	Acceptable – ■■■■■ 2017 not evaluated, ■■■■■ 2014 is acceptable-assessed under 2018 submission

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
					86)	to meet outstanding data requirements for 'Vibrance SB'
Flash point (KCP 2.3.1)	ASTM D93 for Pensky-Martens closed-cup testing	A20607B sedaxane 15.4 g/L, fludioxonil 22.8 g/L, metalaxyl-M 15.1 g/L batch no. SMU7AL007	Not detected below 101°C (Testing was stopped when the substance was observed to be boiling). Not classified as a flammable liquid	Y	██████████ 2017 (VV-467979)  ██████████ 2014 (VV-412230)	Acceptable – ██████████ 2017 not evaluated, ██████████ 2014 is acceptable-assessed under 2018 submission to meet outstanding data requirements for 'Vibrance SB'
Flammability (KCP 2.3.2)	-	-	Not required as the formulation is not a solid nor a gas	-	-	noted
Self-heating (KCP 2.3.3)	IEC 60079-20-1	A20607B sedaxane 15.4 g/L, fludioxonil 22.8 g/L, metalaxyl-M 15.1 g/L batch no. SMU7AL007	Auto-Ignition Temperature: 550 ± 55°C	Y	██████████ 2017 (VV-467979)  ██████████ 2014 (VV-412230)	Acceptable – ██████████ 2017 not evaluated, ██████████ 2014 is acceptable-assessed under 2018 submission to meet outstanding data requirements for 'Vibrance SB'.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L	Acidity (calculated as H <sub>2</sub> SO <sub>4</sub> ): 0.02 % w/w	Y	██████████ 2015 (VV-412229)	Acceptable – assessed under 2018 submission to meet outstanding data



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		batch no. SMU4DP001				requiremetns for 'Vibrance SB'
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	1% w/v in deionized water at 25°C pH = 6.7	Y	[REDACTED] 2015 (VV-412228)	Acceptable – assessed under 2018 submission to meet outstanding data requiremetns for 'Vibrance SB'
			Neat (undiluted) pH = 6.2			
Viscosity (KCP 2.5.1)	CIPAC MT 192	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	At 20°C with shear rate 100 s <sup>-1</sup> : 87.1 mPa.s At 20°C with shear rate 20 s <sup>-1</sup> : 290 mPa.s  At 40°C with shear rate 100 s <sup>-1</sup> : 79.1 mPa.s At 40°C with shear rate 20 s <sup>-1</sup> : 267 mPa.s  The viscosity is significantly depending on the shear rate. Therefore, the test item can be considered as a non-Newtonian liquid	Y	[REDACTED] 2015 (VV-412229)	Acceptable – assessed under 2018 submission to meet outstanding data requiremetns for 'Vibrance SB'
Surface tension (KCP 2.5.2)	EEC A.5	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	0.1% w/v in deionized water at 20°C: 42.2 mN/m 20% w/v in deionized water at 20°C: 28.9 mN/m Undiluted product at 25°C: 28.7 mN/m  The product is surface active.	Y	[REDACTED] 2015 (VV-412229)	Acceptable – assessed under 2018 submission to meet outstanding data requiremetns for 'Vibrance SB'
Relative density (KCP 2.6.1)	OECD 109	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	Density (20°C): 1.032 g/cm <sup>3</sup>	Y	[REDACTED] 2015 (VV-412226)	Acceptable – assessed under 2018 submission to meet outstanding data requiremetns for 'Vibrance SB'
Bulk density	-	-	No study provided since this is only required for a solid formulation	-	-	Noted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.6.2)						
Storage Stability after 14 days at 54° C (KCP 2.7.1)	OECD 113 Analytical method: ST-35/1 and STA-35/2	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	The formulation is physically and chemically stable when stored for 2 weeks at 54°C when stored in packages made of: <ul style="list-style-type: none"> <li>High Density Polyethylene (HDPE)</li> </ul> A summary of the data generated before and after storage is given in the Appendix 3.	N	██████ <b>2015</b> <b>VV-412223</b>	Acceptable – assessed under 2018 submission to meet outstanding data requirements for ‘Vibrance SB’
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not conducted as stable after 14 days at 54°C.	-	-	Noted
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Please refer to KCP 2.7.2	-	-	Noted
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	After storage of 7 days at 0 °C no separation was observed. After 24 h at room temperature after 1 inversion: No separation  After storage: <b>Wet sieve test</b> (CIPAC MT 185): 0.02% residue on a 75 µm sieve	Y	██████ <b>2015</b> <b>(VV-412229)</b>	Acceptable – assessed under 2018 submission to meet outstanding data requirements for ‘Vibrance SB’
Ambient temperature shelf life (KCP 2.7.5)	Analytical method: ST-35/1 and STA-35/2	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	The formulation is physically and chemically stable when stored for 2 and 3 years at 20°C when stored in packages made of: <ul style="list-style-type: none"> <li>High Density Polyethylene (HDPE)</li> </ul> A summary of the data generated before and after storage is given in the Appendix 3 and 5.	N  N	██████ <b>2018</b> <b>(VV-412229)</b>  ██████ <b>2019</b> <b>(VV-472257)</b>	Acceptable – assessed under 2018 submission to meet outstanding data requirements for ‘Vibrance SB’  No details were

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>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 ('Apron XL' 2020 product renewal). 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 above, the applicants case highlighted that all relevant</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>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 -1.3 %; 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</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						<p>formed on storage.</p> <p><b>For future uses, where stored seed is recommended for use in future growing seasons (i.e. retained, 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.</b></p>
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not conducted as stable at ambient tempetaure for two years	-	-	
Wettability (KCP 2.8.1)	-	-	Not applicable as this is only required for a solid formulation to be dispersed or dissolved in water	-	-	
Persistence of foaming	CIPAC MT 47.2	A20607B sedaxane 15.6 g/L,	20% w/v in CIPAC water D: 2 mL after 10 seconds	Y	██████ 2015	Acceptable – assessed under

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.2)		fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	0 mL after 1 minute 0 mL after 3 minutes 0 mL after 12 minutes		(VV-412228)	2018 submission to meet outstanding data requirements for 'Vibrance SB'.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184 (chemical assay) Analytical method ST-35/1	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	20 % w/v in CIPAC water D at 30°C after 0.5 hours: Sedaxan: 100% Fludioxonil: 101% Metalaxyl-M: 101%	Y	██████ 2015 (VV-412228)	Acceptable – assessed under 2018 submission to meet outstanding data requirements for 'Vibrance SB' The in use conc. is noted to be 6 – 15 %; the test was conducted at 20 % w/v, this is broadly in line with the proposed in use concentration.
	CIPAC MT 184 (gravimetrically)		20 % w/v in CIPAC water D at 30 °C after 0.5 hours: 100%	Y	██████ 2015 (VV-412229)	See above
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not relevant for FS formulation	-	-	
Dispersion stability (KCP 2.8.3.3)	-	-	Not applicable as this is only required for SE / OD formulations	-	-	
Degree of dissolution and dilution stability	-	-	Not applicable as this is only required for water soluble formulations	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.8.4)						
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	Laser diffraction method: d(10): 0.74 µm d(50): 2.18 µm d(90): 7.18 µm	Y	██████████ 2015 (VV-412229)	Not required for FS formulation.
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	On a 75 µm sieve: 0.01%	Y	██████████ 2015 (VV-412228)	Acceptable – assessed under 2018 submission to meet outstanding data requirements for ‘Vibrance SB’
Dust content (KCP 2.8.5.2.1)	-	-	Not applicable as this is only required for granular formulations	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not applicable as this is only required for granular formulations	-	-	
Attrition (KCP 2.8.5.3)	-	-	Not applicable as this is only required for granular formulations	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not applicable as this is only required for tablet formulations	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	Not applicable as this is only required for formulations forming emulsions	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	Not applicable as this is only required for formulations forming emulsions	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	--	Not applicable as this is only required for formulations forming emulsions	-	-	



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flowability (KCP 2.8.7.1)	-	-	Not applicable as this is only required for granular formulations	-	-	
Pourability (KCP 2.8.7.2)	CIPAC MT 148	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	Pour residue: 2.3% Rinsed residue: 0.2%	Y	██████████ 2015 (VV-412228)	Acceptable- assessed under 2018 submission to meet outstanding data requiremetns for 'Vibrance SB'
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not applicable as this is only for dustable powders	-	-	
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	A20607B sedaxane 15.6 g/L, fludioxonil 23.3 g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	Adhesion on sugar beet treated seeds: Retention capacity: Sedaxane: 101% Fludioxonil: 100% Metalaxyl-M: 100%	Y	██████████ 2015 (VV-412228)	Acceptable – assessed under 2018 submission to meet outstanding data requiremetns for 'Vibrance SB'
Distribution to seed (KCP 2.10.2)	CIPAC MT 175	A20607B sedaxane 15.6 g/L, fludioxonil 23.3	<b>Seed type: sugar beet</b>  <u>Sedaxane</u>	Y	██████████ 2015 (VV-412229)	Acceptable – assessed under 2018 submission

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		g/L, metalaxyl-M 15.3 g/L batch no. SMU4DP001	<p>Minimum value: 4.58 µg / seed  Maximum value: 7.27 µg / seed  Average absorption value: 5.28 µg / seed  Standard deviation: 0.54  Relative standard deviation: 10.2%</p> <p><u>Fludioxonil</u>  Minimum value: 6.14 µg / seed  Maximum value: 10.4 µg / seed  Average absorption value: 7.40 µg / seed  Standard deviation: 0.83  Relative standard deviation: 11.2%</p> <p><u>Metalaxyl-M</u>  Minimum value 4.01 µg / seed  Maximum value 6.98 µg / seed  Average absorption value 4.96 µg / seed  Standard deviation 0.58  Relative standard deviation: 11.7%</p>			<p>to meet outstanding data requirements for ‘Vibrance SB’</p> <p><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 required for full standard authorisation.</b></p>
Other/special studies (KCP 2.11)	-	-	There is no other / special study	-	-	

### 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	
<b>Name of authority</b>	<b>HSE Chemicals Regulation Division (CRD), UK</b>
<b>Reviewer's comments</b>	<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 10 to 50 L HDPE. 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.</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.</p>

**Table 4.1-1: Packaging information for 10 L canister**

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	240 mm × 180 mm × 375 mm (Length × Width × Height)
Opening:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring
Closure:	Screw cap closure (63 mm diameter)
Seal:	Induction heat seal or compression wad and tamper evident ring
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-2: Packaging information for 20 L canister**

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	295 mm × 245 mm × 400 mm (Length × Width × Height)
Opening:	Screw cap closure DIN 60 with induction heat seal or compression wad and tamper evident ring
Closure:	Screw cap closure DIN 60
Seal:	Induction heat seal or compression wad and tamper evident ring
Manner of construction	extruded

Type	Description
UN/ADR	compliant

**Table 4.1-3: Packaging information for 50 L drum**

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	380 mm × 605 mm (Diameter × Height)
Opening:	2 × Screw cap closure DIN 60 with induction heat seal or compression wad and tamper evident ring
Closure:	DIN 60
Seal:	Induction heat seal or compression wad and tamper evident ring
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-4: Packaging information for 200 L drum**

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	580 mm × 960 mm (Diameter × Height)
Opening:	2 × Screw cap closure DIN 60 with induction heat seal or compression wad and tamper evident ring
Closure:	DIN 60
Seal:	Induction heat seal or compression wad and tamper evident ring
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-5: Packaging information for 500 L rigid Intermediate Bulk Container (RIBC)**

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	1200 mm × 800 mm × 1000 mm (Length × Width × Height)
Opening top:	150 mm with gasket and facility for tamper evidence
Opening bottom:	50mm valve with screw cap
Manner of construction	extruded
UN/ADR	compliant

**Table 4.1-6: Packaging information for 1000 L RIBC**

Type	Description
Material:	High Density Polyethylene (HDPE)
Shape/size:	1200 mm × 1000 mm × 1160 mm (Length × Width × Height)
Opening top:	150 mm with gasket and facility for tamper evidence
Opening bottom:	50mm valve with screw cap

Type	Description
Manner of construction	extruded
UN/ADR	compliant

The packaging for the product A20607B 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 A20607SB for at least 2 years under normal storage conditions. For details please see Appendix 3 and Appendix 4.

## 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	██████	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	SYN
KCP Section 2	██████	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	SYN
KCP 2.1	██████	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	SYN
KCP 2.2	██████	15/08/2017	A20607B - Safety Study Report No. HT17/560 Document No. VV 467979 , A20607B_10253 Test Facility Syngenta Technology & Engineering 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 2.3	██████	15/08/2017	A20607B – Safety Study Report No. HT17/560 Document No. VV 467979 , A20607B_10253 Test Facility Syngenta Technology & Engineering GLP Unpublished	N	SYN
KCP 2.3	██████	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	SYN
KCP 2.4	██████	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	SYN
KCP 2.4	██████	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	SYN
KCP 2.5	██████	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	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 2.6	████████	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	SYN
KCP 2.7	██████	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	SYN
KCP 2.7	██████	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	SYN
KCP 2.7	██████	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	SYN
KCP 2.8.2	██████	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	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
			Unpublished		
KCP 2.8.3	██████	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	SYN
KCP 2.8.3	██████	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	SYN
KCP 2.8.5.1	██████	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	SYN
KCP 2.8.5.1	██████	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	SYN
KCP 2.8.7	██████	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	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
			Unpublished		
KCP 2.10	██████	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	SYN
KCP 2.10	██████	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	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

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

<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</b> <b>Y/N</b>	<b>Owner</b>
KCP 2.2		15/08/2017	A20607B - Safety Study Report No. HT17/560 Document No. VV-467979 , A20607B_10253 Test Facility Syngenta Technology & Engineering GLP Unpublished	N	SYN
KCP 2.3		15/08/2017	A20607B - Safety Study Report No. HT17/560 Document No. VV-467979 , A20607B_10253 Test Facility Syngenta Technology & Engineering GLP Unpublished	N	SYN
KCP 2.2		15/08/2017	A20607B - Safety Study Report No. HT17/560 Document No. VV-467979 , A20607B_10253 Test Facility Syngenta Technology & Engineering GLP Unpublished	N	SYN

**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</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</b> <b>Y/N</b>	<b>Owner</b>
KCP XX	Author	YYYY	Title	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>
			Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished		

## **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.

### Appendix 3 Content of active ingredients and properties before and after storage for 2 weeks at 54°C in HDPE packaging

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

Active Ingredient(s)	Storage conditions	Content of control sample	Content of test sample
Sedaxane (sum of SYN508210 and SYN508211)	Initial	--	15.6 g/L
Sedaxane (sum of SYN508210 and SYN508211)	2 weeks below -10°C	15.5 g/L	--
Sedaxane (sum of SYN508210 and SYN508211)	2 weeks at 54°C	--	15.4 g/L
SYN508210 (trans isomer of sedaxane)	Initial	--	13.4 g/L
SYN508210 (trans isomer of sedaxane)	2 weeks below -10°C	13.3 g/L	
SYN508210 (trans isomer of sedaxane)	2 weeks at 54°C	--	13.2 g/L
SYN508211 (cis isomer of sedaxane)	Initial	--	2.13 g/L
SYN508211 (cis isomer of sedaxane)	2 weeks below -10°C	2.13 g/L	--
SYN508211 (cis isomer of sedaxane)	2 weeks at 54°C	--	2.13 g/L
Fludioxinil	Initial	--	23.3 g/L
Fludioxinil	2 weeks below -10°C	22.9 g/L	--
Fludioxinil	2 weeks at 54°C	--	22.9 g/L
Metalaxyl-M including its S-enantiomer	Initial	--	15.8 g/L
Metalaxyl-M including its S-enantiomer	2 weeks below -10°C	15.6 g/L	--
Metalaxyl-M including its S-enantiomer	2 weeks at 54°C	--	15.6 g/L
Metalaxyl-M	Initial	--	15.3 g/L
Metalaxyl-M	2 weeks below -10°C	15.1 g/L	--
Metalaxyl-M	2 weeks at 54°C	--	15.1 g/L
S-enantiomer (CGA351920)	Initial	--	0.51 g/L
S-enantiomer (CGA351920)	2 weeks below -10°C	0.50 g/L	--
S-enantiomer (CGA351920)	2 weeks at 54°C	--	0.51 g/L

#### Observations and Conclusion

All the values are well within the analytical error and show no decomposition.



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

PTest Description	Method	Initial Results	Results after 2 weeks at 54°C
<b>Color</b>	Visual	Light grey	Light grey
<b>Odor</b>	Organoleptic	Slightly sweetish	Slightly sweetish
<b>Physical State</b>	Visual	Mild	Mild
<b>Appearance</b>	Visual	--	No claying, easily redispersible
<b>pH Value</b> Concentration: 1% Deionized Water	CIPAC MT 75.3	6.7	6.5
<b>pH Value</b> Undiluted	CIPAC MT 75.3	6.2	6.0
<b>Relative Density</b> Temperature: 20°C	OECD 109	1.032 g/cm <sup>3</sup>	1.031 g/cm <sup>3</sup>
<b>Wet Sieve Test</b> Sieve Size: 75 µm	CIPAC MT 185	0.01 %	< 0.01%
<b>Pourability</b> Pour Residue Rinsed Residue	CIPAC MT 148	Pour: 2.30% Rinsed: 0.20%	Pour: 2.00% Rinsed: 0.12%
<b>Suspensibility</b> Concentration: 20% CIPAC Water D Temperature: 30°C Waiting Period: 30 min. Sedaxane Fludioxonil Metalaxyl-M	CIPAC MT 184 (chemical assay)	100% 101% 101%	100% 100% 100%
<b>Adhesion to Seeds (sugar beet)</b> Retention Capacity of: Sedaxane Fludioxonil Metalaxyl-M	CIPAC MT 194 (chemical assay)	101% 100% 100%	100% 100% 98%

### Observations and Conclusion

No significant changes of the physical and technical properties were found after storage.

**Table A3-3: Packaging Evaluation after storage for 2 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)	0.01% (weight gain)
Permeation through the container walls	None

### Observations and Conclusion

The packaging material proved to be resistant to its content.

## Appendix 4 Content of active ingredients and properties before and after storage for 2 years at 20°C in HDPE packaging

**Table A4-1: Content of active substances before and after storage for two years at 20°C in HDPE packaging**

Active Ingredient(s)	Storage conditions	Content of control sample	Content of test sample
<b>Sedaxane</b> (sum of SYN508210 and SYN508211)	Initial	--	1.51% w/w corresponding to 15.6 g/L
<b>Sedaxane</b> (sum of SYN508210 and SYN508211)	2 years below -10°C	1.49% w/w corresponding to 15.4 g/L	--
<b>Sedaxane</b> (sum of SYN508210 and SYN508211)	2 years at 20°C	--	1.49% w/w corresponding to 15.4 g/L
<b>SYN508210</b> (trans isomer of sedaxane)	Initial	--	1.30% w/w corresponding to 13.4 g/L
<b>SYN508210</b> (trans isomer of sedaxane)	2 years below -10°C	1.28% w/w corresponding to 13.2 g/L	--
<b>SYN508210</b> (trans isomer of sedaxane)	2 years at 20°C	--	1.28% w/w corresponding to 13.2 g/L
<b>SYN508211</b> (cis isomer of sedaxane)	Initial	--	0.206% w/w corresponding to 2.13 g/L
<b>SYN508211</b> (cis isomer of sedaxane)	2 years below -10°C	0.206% w/w corresponding to 2.13 g/L	--
<b>SYN508211</b> (cis isomer of sedaxane)	2 years at 20°C	--	0.206% w/w corresponding to 2.13 g/L
<b>Fludioxinil</b>	Initial	--	2.26% w/w corresponding to 23.3 g/L
<b>Fludioxinil</b>	2 years below -10°C	2.22% w/w corresponding to 22.9 g/L	--
<b>Fludioxinil</b>	2 years at 20°C	--	2.22% w/w corresponding to 22.9 g/L
<b>Metalaxyl-M including its S-enantiomer</b>	Initial	--	1.53% w/w corresponding to 15.8 g/L
<b>Metalaxyl-M including its S-enantiomer</b>	2 years below -10°C	1.50% w/w corresponding to 15.5 g/L	--
<b>Metalaxyl-M including its S-enantiomer</b>	2 years at 20°C	--	1.51% w/w corresponding to 15.6 g/L
<b>Metalaxyl-M</b>	Initial	--	1.48% w/w corresponding to 15.3 g/L
<b>Metalaxyl-M</b>	2 years below -10°C	1.45% w/w corresponding to 15.0 g/L	--

<b>Metalaxyl-M</b>	2 years at 20°C	--	1.46% w/w corresponding to 15.1 g/L
<b>S-enantiomer (CGA351920)</b>	Initial	--	0.049% w/w corresponding to 0.51 g/L
<b>S-enantiomer (CGA351920)</b>	2 years below -10°C	0.050% w/w corresponding to 0.52 g/L	--
<b>S-enantiomer (CGA351920)</b>	2 years at 20°C	--	0.050% w/w corresponding to 0.52 g/L

### Observations and Conclusion

All the values are well within analytical error and show no decomposition.

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

Test Description	Method	Initial Results	Results after 2 years at 20°C
<b>Color</b>	Visual	Light grey	Light grey
<b>Odor</b>	Organoleptic	Slightly sweetish	Slightly sweetish
<b>Physical State</b>	Visual	Mild	Mild
<b>Appearance</b>	Visual	--	No claying, easily redispersible
<b>pH Value</b> Concentration: 1% Deionized water	CIPAC MT 75.3	6.7	6.6
<b>pH Value</b> Undiluted	CIPAC MT 75.3	6.2	6.1
<b>Relative Density</b> Temperature: 20°C	OECD 109	1.032 g/cm <sup>3</sup>	1.032 g/cm <sup>3</sup>
<b>Wet Sieve Test</b> Sieve size: 75 µm	CIPAC MT 185	0.01%	0.03%
<b>Pourability</b> Pour residue Rinsed Residue	CIPAC MT 148	Pour: 2.30% Rinsed: 0.20%	Pour: 3.10% Rinsed: 0.17%
<b>Suspensibility</b> Concentration: 20% CIPAC Water D Temperature: 30°C Waiting period: 30 min. Sedaxane Fludioxonil Metalaxyl-M	CIPAC MT 184 (chemical assay)	100% 101% 101%	99% 99% 99%
<b>Adhesion to Seeds (sugar beet)</b> Retention capacity of: Sedaxane Fludioxonil Metalaxyl-M	CIPAC MT 194 (chemical assay)	101% 100% 100%	100% 100% 102%

### Observations and Conclusion

No significant changes of the physical and technical properties were found after storage.

**Table A4-3: Packaging Evaluation after storage for 2 years at 20°C in HDPE packaging**

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

Evaluation Criteria	Results after 2 years at 20°C
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)	0.01% (weight loss)
Permeation through the container walls	None

### Observations and Conclusion

The packaging material proved to be resistant to its content.

## Appendix 5 Content of active ingredients and properties before and after storage for 3 years at 20°C in HDPE packaging

**Table A5-1: Content of active substances before and after storage for 3 years at 20°C in HDPE packaging**

Active Ingredient(s)	Storage conditions	Content of control sample	Content of test sample
<b>Sedaxane</b> (sum of SYN508210 and SYN508211)	Initial	--	1.51% w/w corresponding to 15.6 g/L
<b>Sedaxane</b> (sum of SYN508210 and SYN508211)	2 years below -10°C	1.47% w/w corresponding to 15.2 g/L	--
<b>Sedaxane</b> (sum of SYN508210 and SYN508211)	2 years at 20°C	--	1.47% w/w corresponding to 15.2 g/L
<b>SYN508210</b> (trans isomer of sedaxane)	Initial	--	1.30% w/w corresponding to 13.4 g/L
<b>SYN508210</b> (trans isomer of sedaxane)	2 years below -10°C	1.27% w/w corresponding to 13.1 g/L	--
<b>SYN508210</b> (trans isomer of sedaxane)	2 years at 20°C	--	1.27% w/w corresponding to 13.1 g/L
<b>SYN508211</b> (cis isomer of sedaxane)	Initial	--	0.206% w/w corresponding to 2.13 g/L
<b>SYN508211</b> (cis isomer of sedaxane)	2 years below -10°C	0.202% w/w corresponding to 2.08 g/L	--
<b>SYN508211</b> (cis isomer of sedaxane)	2 years at 20°C	--	0.202% w/w corresponding to 2.08 g/L
<b>Fludioxinil</b>	Initial	--	2.26% w/w corresponding to 23.3 g/L
<b>Fludioxinil</b>	2 years below -10°C	2.22% w/w corresponding to 22.9 g/L	--
<b>Fludioxinil</b>	2 years at 20°C	--	2.22% w/w corresponding to 22.9 g/L
<b>Metalaxyl-M including its S-enantiomer</b>	Initial	--	1.53% w/w corresponding to 15.8 g/L
<b>Metalaxyl-M including its S-enantiomer</b>	2 years below -10°C	1.51% w/w corresponding to 15.6 g/L	--
<b>Metalaxyl-M including its S-enantiomer</b>	2 years at 20°C	--	1.52% w/w corresponding to 15.7 g/L
<b>Metalaxyl-M</b>	Initial	--	1.48% w/w corresponding to 15.3 g/L
<b>Metalaxyl-M</b>	2 years below -10°C	1.46% w/w corresponding to 15.1 g/L	--

<b>Metalaxyl-M</b>	2 years at 20°C	--	1.47% w/w corresponding to 15.2 g/L
<b>S-enantiomer (CGA351920)</b>	Initial	--	0.049% w/w corresponding to 0.51 g/L
<b>S-enantiomer (CGA351920)</b>	2 years below -10°C	0.048% w/w corresponding to 0.495 g/L	--
<b>S-enantiomer (CGA351920)</b>	2 years at 20°C	--	0.049% w/w corresponding to 0.51 g/L

## Observations and Conclusion

All the values are well within analytical error and show no decomposition.

**Table A5-2: Physical and technical properties before and after storage for 3 years at 20°C in HDPE packaging**

Test Description	Method	Initial Results	Results after 3 years at 20°C
<b>Color</b>	Visual	Light grey	Light grey
<b>Odor</b>	Organoleptic	Mild	Mild
<b>Physical State</b>	Visual	Liquid	Liquid
<b>Appearance</b>	Visual	--	No claying, easily redispersible
<b>pH Value</b> Concentration: 1% Deionized water	CIPAC MT 75.3	6.7	6.7
<b>pH Value</b> Undiluted	CIPAC MT 75.3	6.2	6.1
<b>Relative Density</b> Temperature: 20°C	OECD 109	1.032 g/cm <sup>3</sup>	1.032 g/cm <sup>3</sup>
<b>Wet Sieve Test</b> Sieve size: 75 µm	CIPAC MT 185	0.01%	0.01%
<b>Pourability</b> Pour residue Rinsed Residue	CIPAC MT 148	Pour: 2.30% Rinsed: 0.20%	Pour: 2.8% Rinsed: 0.10%
<b>Suspensibility</b> Concentration: 20% CIPAC Water D Temperature: 30°C Waiting period: 30 min. Sedaxane Fludioxonil Metalaxyl-M	CIPAC MT 184 (chemical assay)	100% 101% 101%	99% 99% 99%
<b>Adhesion to Seeds (sugar beet)</b> Retention capacity of: Sedaxane Fludioxonil Metalaxyl-M	CIPAC MT 194 (chemical assay)	101% 100% 100%	101% 100% 101%

## Observations and Conclusion

No significant changes of the physical and technical properties were found after storage.

**Table A5-3: Packaging Evaluation after storage for 3 years at 20°C in HDPE packaging**

Evaluation Criteria	Results after 3 years at 20°C
Color change of the packaging	None

Evaluation Criteria	Results after 3 years at 20°C
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)
Permeation through the container walls	None

### Observations and Conclusion

The packaging material proved to be resistant to its content.