

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: A23109A

Product name: ORONDIS VIP

Chemical active substances:

Metalaxyl-M, 174.4 g/L

Oxathiapiprolin, 30.0 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorisation)

Applicant: Syngenta

Submission date: June 2022, Updated July 2024

MS Finalisation date: July 2023 (initial Core Assessment)

December 2023 (final Core Assessment)

updated July 2024

Version history

When	What
July 2022	Version 1 Applicant dRR submitted by applicant to the Polish Ministry of Agriculture and Rural Development
July 2023	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.
December 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are struck through and shaded for transparency.
July 2024	Applicant Update: 4.1.1: Addition of Packaging Information – correction of packaging size (1 L) - highlighted in turquoise.
July 2024	Final report - updated with regard to the provisions of COMMISSION IMPLEMENTING REGULATION (EU) 2024/1718 of 19 June 2024 amending Implementing Regulations (EU) 2020/617 and (EU) No 540/2011 as regards the conditions of approval of the active substance metalaxyl-M. Additional information/assessments included by the zRMS in the report are highlighted in green. Not agreed or not relevant information are struck through and shaded for transparency.

Table of Contents

1	Section 1: Identity of the plant protection product	4
1.1	Applicant (KCP 1.1).....	4
1.2	Producer of the plant protection product and of the active substances (KCP 1.2)	4
1.2.1	Producer(s) of the preparation	4
1.2.2	Producer(s) of the active substance(s)	4
1.2.3	Statement of purity (and detailed information on impurities) of the active substance(s)	4
1.2.3.1	Metalaxyl-M	4
1.2.3.2	Oxathiapiprolin.....	5
1.3	Trade names and producer's development code numbers for the preparation (KCP 1.3).....	5
1.4	Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4).....	5
1.4.1	Composition of the plant protection product (KCP 1.4.1).....	6
1.4.2	Information on the active substance(s) (KCP 1.4.2).....	6
1.4.3	Information on safeners, synergists and co-formulants (KCP 1.4.3).....	6
1.5	Type and code of the plant protection product (KCP 1.5).....	6
1.6	Function (KCP 1.6)	6
2	Section 2: Physical, chemical and technical properties of the plant protection product	7
3	Section 3 is presented as a separate document.....	19
4	Section 4: Further information on the plant protection product	20
4.1	Packaging and Compatibility with the Preparation (KCP 4.4).....	20
Appendix 1	Lists of data considered in support of the evaluation.....	21
Appendix 2	Additional data on the physical, chemical and technical properties of the active substance	27
Appendix 3	Storage stability data before and after storage at 54°C in HDPE packaging ..	28
Appendix 4	Storage stability data before and after storage over 2 years at 25°C in HDPE packaging	30

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

Noticed data gaps are: **none.**

~~— Ambient temperature shelf life: A storage stability study for 3y at ambient temperature has been initiated on 25th of September 2020 to demonstrate fitness for use up to 3 years.~~

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Syngenta Crop Protection AG
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CH 4058 Basel
Switzerland

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

Telephone no.: +41 (0) 61 323 0675

E-mail: [xxxxxxxxxxxx](#)

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

1.2.1 Producer(s) of the preparation

Name: Syngenta Crop Protection AG

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

1.2.2 Producer(s) of the active substance(s)

Metalaxyl-M

Name: Syngenta Crop Protection AG

Oxathiapiprolin

Name: Corteva Agriscience International Sàrl (formally DuPont Operations Sàrl)

Confidential information or data to the above listed producers are provided separately (Part C or letter of access/supply).

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

1.2.3.1 Metalaxyl-M

Test Substance	EU agreed minimum purity Reference: COMMISSION IMPLEMENTING REGULATION (EU) 2020/617
Metalaxyl-M	≥ 920 g/kg
2,6-dimethylphenylamine	≤ 0.5 g/kg
	in formulated material: ≤ 0.09 g/kg

4-methoxy-5-methyl-5H-[1,2]oxathiole 2,2-dioxide	≤ 1 g/kg
	in formulated material: ≤ 0.18 g/kg
2-[(2,6-dimethyl-phenyl)-(2-methoxyacetyl)-amino]-propionic acid 1-methoxycarbonyl-ethyl ester ¹	≤ 0.18 g/kg 10 g/kg
	in formulated material: ≤ 0.03 g/kg 1.8 g/kg

¹ As stated in Commission Implementing Regulation (EU) 2024/1718 of 19 June 2024 amending Implementing Regulations (EU) 2020/617 and (EU) No 540/2011 as regards the conditions of approval of the active substance metalaxyl-M, Annex 1 of the Metalaxyl-M Implementing Regulation (EU) 2020/617, an on going EU evaluation under Article 7 (submission of documentation 25th July 2020) is being finalized. The RMS Belgium concluded that impurity 2-[(2,6 dimethyl phenyl) (2-methoxyacetyl) amino] propionic acid 1-methoxycarbonyl-ethyl ester (CGA226048) is shown to be non-genotoxic and non-relevant and an updated RAR has been made available in May 2021 for public commenting. Therefore, this substance is not considered as a relevant impurity in the product A23109A. However, this conclusion has not yet been implemented in a new or adapted EU regulation.

Pure Metalaxyl-M in A23109A

content of pure active substance:	174.4 g/L	16.24 % w/w*
limits :	163.9 – 184.9 g/L	15.27 – 17.21 % w/w*

* Based on the density of the formulation = 1.074 g/cm³

Technical Metalaxyl-M in A23109A

at a minimum purity of the technical active substance of 92.0 % w/w.		
content of technical active substance:	189.6 g/L	17.65 % w/w*
limits :	178.2 – 201.0 g/L	16.59 – 18.71 % w/w*

* Based on the density of the formulation = 1.074 g/cm³

1.2.3.2 Oxathiapiprolin

Test Substance	EU agreed minimum purity Reference: COMMISSION IMPLEMENTING REGULATION (EU) 2017/239
Oxathiapiprolin	≥ 950 g/kg

Pure Oxathiapiprolin in A23109A

content of pure active substance:	30.0 g/L	2.79 % w/w*
limits :	27.0 – 33.0 g/L	2.51 – 3.07 % w/w*

* Based on the density of the formulation = 1.074 g/cm³

Technical Oxathiapiprolin in A23109A

at a minimum purity of the technical active substance of 95.0 % w/w.		
content of technical active substance:	31.58 g/L	2.94 % w/w*
limits :	28.42 – 34.74 g/L	2.65 – 3.23 % w/w*

* Based on the density of the formulation = 1.074 g/cm³

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

Trade name: ORONDIS VIP

Company code number: A23109A

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 A23109A was not evaluated previously as a representative formulation (same uses and same GAPs) during the EU review of the active substances Oxathiapiprolin and Metalaxyl-M.

The content of Metalaxyl-M and Oxathiapiprolin in A23109A 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)

Table 1.4-1: Information on Metalaxyl-M

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

Table 1.4-2: Information on Oxathiapiprolin

Type	Name/Code Number	
ISO common name	Oxathiapiprolin	Variant: not relevant
CAS No.	1003318-67-9	
EC No.	801-263-1	
CIPAC No.	985	

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

Table 1.4-3: Information on safeners/ synergists / co-formulant

Type	Name/Code Number	
Safener /synergist	None	
ISO common name		
CAS No.		
EC No.		

CONFIDENTIAL information is provided separately (Part C).

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

Type: Dispersible concentrate

[Code: DC]

1.6 Function (KCP 1.6)

Fungicide.

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a brownish, clear liquid, with a slightly chemical odour. It is not explosive, has no oxidising properties. The product has no flash point below 200°C. It has an auto-ignition temperature of 400°C ± 12°C. In aqueous solution, it has a pH value around 4.3 at 25°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C, 14 and 28 days at 54 °C, neither the active ingredient content nor the technical properties changed. The stability data indicate a shelf life of at least 2 3 years at ambient temperature when stored in high density polyethylene (HDPE) packaging. Its technical characteristics are acceptable for a DC formulation.

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

~~The accelerated stability data indicate a shelf life of at least 3 years at ambient temperature when stored in HDPE. However, the final decision on acceptance of the 3 years of storage should be made at the national level. A 2 year storage period can be granted.~~

The intended concentration of use is 0.06 % v/v to 0.25 % v/v.

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

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

Notifier Proposals for Risk and Safety Phrases (KCP 12)

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

Compliance with FAO specifications:

There is no FAO specification for A23109A.

Formulation used for tests

Physico-chemical studies have been conducted with the A23109A (Batch: JHU003-044-001)
The detailed composition of A23109A is shown in the **Confidential Part C**.

The following batches have been used in the physico-chemical studies:

A23109A (oxathiapiprolin/metalaxyl-M DC (030/180)), batch no. JHU003-044-001,;oxathiapiprolin content 2.86% w/w corresponding to 30.7 g/L and metalaxyl-M 16.9% w/w corresponding to 181.5 g/L
(Ravikumar M.A., 2021, Report No SMG16480, Syngenta File No VV-903866)

Composition of the batch is described in **Part C** as confidential information.

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 batch JHU003-044-001.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual and organoleptic assessment	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	Colour: Brownish Physical State: Liquid Appearance: Clear Odor: Slightly chemical	Y	<i>Ravikumar M.A. 2021</i> <i>VV-903873</i>	Accepted.
Explosive properties (KCP 2.2.1)	ASTM E537	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	<u>Differential Scanning Calorimetry:</u> Heat of Decomposition: 86 J/g The heat of decomposition is less than 500 J/g, in which case no further testing is necessary. Not classified as an explosive substance.	Y	<i>Jackson W. 2020</i> <i>VV-903887</i>	Accepted. A23109A is not explosive.
Oxidizing properties (KCP 2.2.2)	UN Test O.2 (Transport of Dangerous Goods, Manual of Tests and Criteria, Part III, Sect. 34, UN 1995)	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	The test item ORONDIS VIP has no oxidising properties according to UN Transport regulation, Devision 5.1. Not classified as an oxidizing substance.	Y	<i>Jackson W. 2020</i> <i>VV-903887</i>	Accepted. A23109A has no oxidizing properties.
Flash point (KCP 2.3.1)	ASTM D3828 (Setaflash) closed-cup testing	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	Not detected below 200°C The test substance is not classified as a flammable liquid in terms of its flash point.	Y	<i>Jackson W. 2020</i> <i>VV-903887</i>	Accepted. The formulation is not flammable.
Flammability (KCP 2.3.2)	ASTM D3828 (Setaflash) closed-cup testing	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	The test substance is not classified as a flammable liquid in terms of its flash point.	Y	<i>Jackson W. 2020</i> <i>VV-903887</i>	Accepted.
Self-heating (KCP 2.3.3)	ISO/IEC 80079-20-1	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	Auto-Ignition Temperature: 400 ± 12°C	Y	<i>Jackson W. 2020</i> <i>VV-903887</i>	Accepted. The formulation does not need to be classified according to Reg. (EC) 1272/2008, in line with the tests/requirements in the UN-RTDG manual.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	Batch: JHU003-044-001 Oxathiapiroline: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	0.11 % w/w (calculated as H ₂ SO ₄)	Y	<i>Ravikumar M.A. 2021 VV-903874</i>	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Batch: JHU003-044-001 Oxathiapiroline: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	1% w/v in deionized water at 25°C: pH = 4.3 undiluted at 25°C: pH = 7.7	Y	<i>Ravikumar M.A. 2021 VV-903873</i>	Accepted.
	CIPAC MT 75.3	Batch: JHU003-044-001 Oxathiapiroline: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	1% w/v in deionized water at 25°C: pH = 4.4 undiluted at 25°C: pH = 7.4	Y	<i>Ravikumar M.A. 2021 VV-903874</i>	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																																																																								
Viscosity (KCP 2.5.1)	OECD 114	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	<div> <p>Shear rate ramped down from 200 to 100 s⁻¹: Mean η = 26.5 mPa.s (at 20°C) Mean η = 11.3 mPa.s (at 40°C)</p> <table border="1"> <thead> <tr> <th colspan="3">Viscosity at 20 °C</th> <th colspan="2">Viscosity at 40 °C</th> </tr> <tr> <th>Shear rate [s⁻¹]</th> <th>1st measure-ment [mPa.s]</th> <th>2nd measure-ment</th> <th>1st measure-ment [mPa.s]</th> <th>2nd measure-ment [mPa.s]</th> </tr> </thead> <tbody> <tr><td>200</td><td>26.52</td><td>26.68</td><td>11.49</td><td>11.33</td></tr> <tr><td>195</td><td>26.55</td><td>26.63</td><td>11.46</td><td>11.30</td></tr> <tr><td>190</td><td>26.51</td><td>26.67</td><td>11.43</td><td>11.35</td></tr> <tr><td>185</td><td>26.54</td><td>26.63</td><td>11.48</td><td>11.31</td></tr> <tr><td>180</td><td>26.49</td><td>26.58</td><td>11.45</td><td>11.28</td></tr> <tr><td>175</td><td>26.44</td><td>26.62</td><td>11.42</td><td>11.33</td></tr> <tr><td>170</td><td>26.48</td><td>26.57</td><td>11.39</td><td>11.29</td></tr> <tr><td>165</td><td>26.42</td><td>26.61</td><td>11.35</td><td>11.26</td></tr> <tr><td>160</td><td>26.46</td><td>26.56</td><td>11.31</td><td>11.21</td></tr> <tr><td>155</td><td>26.40</td><td>26.60</td><td>11.27</td><td>11.27</td></tr> <tr><td>150</td><td>26.44</td><td>26.54</td><td>11.33</td><td>11.23</td></tr> <tr><td>145</td><td>26.37</td><td>26.59</td><td>11.29</td><td>11.18</td></tr> <tr><td>140</td><td>26.42</td><td>26.53</td><td>11.24</td><td>11.24</td></tr> <tr><td>135</td><td>26.35</td><td>26.58</td><td>11.31</td><td>11.19</td></tr> <tr><td>130</td><td>26.39</td><td>26.63</td><td>11.26</td><td>11.26</td></tr> <tr><td>125</td><td>26.31</td><td>26.44</td><td>11.21</td><td>11.21</td></tr> <tr><td>120</td><td>26.36</td><td>26.49</td><td>11.15</td><td>11.15</td></tr> <tr><td>115</td><td>26.41</td><td>26.55</td><td>11.22</td><td>11.22</td></tr> <tr><td>110</td><td>26.47</td><td>26.47</td><td>11.16</td><td>11.16</td></tr> <tr><td>105</td><td>26.38</td><td>26.53</td><td>11.09</td><td>11.09</td></tr> <tr><td>100</td><td>26.44</td><td>26.60</td><td>11.17</td><td>11.17</td></tr> <tr> <td>Mean value</td> <td colspan="2">26.5</td> <td colspan="2">11.3</td> </tr> </tbody> </table> <p>The viscosity is not significantly depending on the shear rate. The test item can be considered as a Newtonian liquid.</p> <p>Kinematic viscosity The kinematic viscosity was calculated (d=1.074 g/cm³) At 20°C with shear rate 100-200 s⁻¹: 24.7 mm²/s At 40°C with shear rate 100-200 s⁻¹: 10.5 mm²/s</p> <p>Equipment The test was performed using the “Brookfield Engineering Labs” Viscometer (Model: DV-II+ Pro) with the “Small Sample Adapter” DIN-82. The shear rate was ramped down from 200 to 100 s⁻¹</p> </div>	Viscosity at 20 °C			Viscosity at 40 °C		Shear rate [s ⁻¹]	1 st measure-ment [mPa.s]	2 nd measure-ment	1 st measure-ment [mPa.s]	2 nd measure-ment [mPa.s]	200	26.52	26.68	11.49	11.33	195	26.55	26.63	11.46	11.30	190	26.51	26.67	11.43	11.35	185	26.54	26.63	11.48	11.31	180	26.49	26.58	11.45	11.28	175	26.44	26.62	11.42	11.33	170	26.48	26.57	11.39	11.29	165	26.42	26.61	11.35	11.26	160	26.46	26.56	11.31	11.21	155	26.40	26.60	11.27	11.27	150	26.44	26.54	11.33	11.23	145	26.37	26.59	11.29	11.18	140	26.42	26.53	11.24	11.24	135	26.35	26.58	11.31	11.19	130	26.39	26.63	11.26	11.26	125	26.31	26.44	11.21	11.21	120	26.36	26.49	11.15	11.15	115	26.41	26.55	11.22	11.22	110	26.47	26.47	11.16	11.16	105	26.38	26.53	11.09	11.09	100	26.44	26.60	11.17	11.17	Mean value	26.5		11.3		Y	Ravikumar M.A. 2021 VV-903874	Accepted. The test item can be considered as a Newtonian liquid.
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Surface tension (KCP 2.5.2)	EEC A.5	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	38.9 mN/m (0.4 % w/v in pure water at 20°C) 40.4 mN/m (0.1 % w/v in pure water at 20°C) 35.7 mN/m (undiluted at 20°C) According to EEC guideline A.5 the preparation should be classified as a surface active material.	Y	Ravikumar M.A. 2021 VV-903874	Accepted. The formulation is surface active.
Relative density (KCP 2.6.1)	OECD 109	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	1.074 g/cm ³ (at 20°C) Relative density: 1.074 Equipment/methodology: oscillation-type density meter	Y	Breedt C. 2021 VV-903892	Accepted.
Bulk density (KCP 2.6.2)	Not applicable as this is only required for a solid formulation.					-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.4	Batch: JHU003-044-001 Oxathiapiiprolin: 2.86 % w/w Metalaxyl-M: 16.9 % w/w	<p>The formulation undergoes no significant physical or chemical change in the packaging material HDPE with regards to content, colour, odor, physical state, appearance, pH value, density, wet sieving, persistent foaming and dispersion stability.</p> <p>Considering the chemical structure of the relevant impurities, the formation of the relevant impurities can be clearly excluded. The relevant impurities can only be formed during the manufacturing synthesis of the respective active substance, due to the given reaction conditions and presence of adequate reaction partners. Under the conditions of formulation manufacturing and storage, such chemical conversions, that would lead to the formation of these impurities, ie bond cleavages and chemical reactions, can be ruled out with certainty.</p> <p>For detailed results see Appendix 3.</p>	Y	Breedt C. 2021 VV-903892	<p>Accepted.</p> <p>The product showed no significant physical changes after accelerated storage. No significant changes were observed in the HDPE packaging and therefore it can be concluded that the test item was not corrosive to the container material. No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage. The accelerated stability data indicate a shelf life of at least 3 years at ambient temperature when stored in HDPE. However, the final decision on acceptance of the 3 years of storage should be made at the national level. A 2-year storage period can be granted.</p>
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.4	Batch: JHU003-044-001 Oxathiapiiprolin: 2.86 % w/w Metalaxyl-M: 16.9 % w/w	<p>The formulation undergoes no significant physical or chemical change during storage at 54°C for 4 weeks in the packaging material HDPE with regards to content, colour, odor, physical state, appearance, pH value, density, wet sieving, persistent foaming and dispersion stability.</p> <p>For detailed results see Appendix 3.</p>	Y	Breedt C. 2021 VV-903892	<p>Please refer to the point 2.7.1.</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Minimum content after heat stability testing (KCP 2.7.3)	Analytical method SF-1027/2	Batch: JHU003-044-001 Oxathiapiprolin: 2.86 % w/w Metalaxyl-M: 16.9 % w/w	The active substance content did not decline to less than 95 % of the initial content. Packaging material: HDPE For detailed results see Appendix 3.	Y	Breedt C. 2021 VV-903892	Accepted.
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	After storage of 7 days at 0°C ± 2°C no separation was observed. After allowing the test sample to reach room temperature over a period of 24 h and inverting once no separation was observed. Wet sieve test: < 0.01% on a 75 µm sieve.	Y	Ravikumar M.A. 2021 VV-903874	Accepted.
Ambient temperature shelf life (KCP 2.7.5)	-	-	In accordance with international guidelines, extrapolation of the chemical, physico-chemicals and packaging properties after storage for 2 weeks at 54°C indicate that for a period of at least two years the product remains suitable for use and continues to comply with the specification. Extrapolation of the chemical, physico-chemical and packaging properties after storage for 4 weeks at 54°C indicate that for a period of at least three years the product remains suitable for use and continues to comply with the specification, if stored in an unopened original container, away from direct sunlight and following the product instructions during transport and storage. A storage stability study for 3y at ambient temperature has however been initiated on 25 th of September 2020 to demonstrate fitness for use up to 3 years.	Y	Breedt C. 2021 VV-903892	Stability study at ambient temperature is ongoing. A storage stability study for 3y at ambient temperature has been initiated on 25 th of September 2020 to demonstrate stability for use up to 3 years.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	<p>The formulation is physically and chemically stable after storage for two years at 25°C in the following packaging material: -High density polyethylene pack (HDPE)</p> <p>For full details, please see Appendix 4</p> <p>Findings of the present ambient study confirms a shelf life of at least 2 years. Based on previous findings of prolonged accelerated storage studies (300185324), a shelf life of at least 3 years has been assigned</p> <p>Considering the chemical structure of the relevant impurities, the formation of the relevant impurities can be clearly excluded.</p> <p>The relevant impurities can only be formed during the manufacturing synthesis of the respective active substance, due to the given reaction conditions and presence of adequate reaction partners. Under the conditions of formulation manufacturing and storage, such chemical conversions, that would lead to the formation of these impurities, ie bond cleavages and chemical reactions, can be ruled out with certainty.</p>	Y	Breedt C. 2023 VV-982143	<p>Accepted.</p> <p>The product showed no significant physical changes after storage.</p> <p>No significant changes were observed in the HDPE packaging and therefore it can be concluded that the test item was not corrosive to the container material.</p> <p>No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage.</p> <p>The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE.</p>
Shelf life in months (if less than 2 years) (KCP 2.7.6)	Please refer to KCP 2.7.5.					-
Wettability (KCP 2.8.1)	Not applicable as this is not required for DC formulation.					-
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	<p>0.1 % w/v in CIPAC water D: After 1 minute: 56 mL After 12 minutes: 52 mL</p> <p>0.4 % w/v in CIPAC water D: After 1 minute: 42 mL After 12 minutes: 40 mL</p>	Y	Ravikumar M.A. 2021 VV-903873	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																				
Suspensibility (KCP 2.8.3.1)	Not applicable as this is not required for DC formulation.					-																																				
Spontaneity of dispersion (KCP 2.8.3.2)	Not applicable as this is not required for DC formulation.					-																																				
Dispersion stability (KCP 2.8.3.3)	CIPAC MT 180	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	<table><tr><td colspan="3">0.1 % w/v (at 25°C)</td></tr><tr><td></td><td>CIPAC A water</td><td>CIPAC D water</td></tr><tr><td>Initial Dispersion</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h</td><td>No cream No oil No sediment</td><td>No cream No oil No sediment</td></tr><tr><td>Re-dispersion after 24 h</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h after Re-dispersion</td><td>No cream No oil No sediment</td><td>No cream No oil No sediment</td></tr><tr><td colspan="3">0.4 % w/v (at 25°C)</td></tr><tr><td></td><td>CIPAC A water</td><td>CIPAC D water</td></tr><tr><td>Initial Dispersion</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h</td><td>No cream No oil No sediment</td><td>No cream No oil No sediment</td></tr><tr><td>Re-dispersion after 24 h</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h after Re-dispersion</td><td>No cream No oil No sediment</td><td>No cream No oil No sediment</td></tr></table>	0.1 % w/v (at 25°C)				CIPAC A water	CIPAC D water	Initial Dispersion	Complete	Complete	0.5 h	No cream No oil No sediment	No cream No oil No sediment	Re-dispersion after 24 h	Complete	Complete	0.5 h after Re-dispersion	No cream No oil No sediment	No cream No oil No sediment	0.4 % w/v (at 25°C)				CIPAC A water	CIPAC D water	Initial Dispersion	Complete	Complete	0.5 h	No cream No oil No sediment	No cream No oil No sediment	Re-dispersion after 24 h	Complete	Complete	0.5 h after Re-dispersion	No cream No oil No sediment	No cream No oil No sediment	Y	Ravikumar M.A. 2021 VV-903873	Accepted.
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Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																				
	CIPAC MT 180	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	<table><tr><td colspan="3">0.1 % w/v (at 25°C)</td></tr><tr><td></td><td>CIPAC A water</td><td>CIPAC D water</td></tr><tr><td>Initial Dispersion</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h</td><td>No cream No oil No sediment</td><td>No cream No oil No sediment</td></tr><tr><td>Re-dispersion after 24 h</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h after Re-dispersion</td><td>No cream No oil No sediment</td><td>No cream No oil No sediment</td></tr></table> <table><tr><td colspan="3">0.4 % w/v (at 25°C)</td></tr><tr><td></td><td>CIPAC A water</td><td>CIPAC D water</td></tr><tr><td>Initial Dispersion</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h</td><td>No cream No oil No sediment</td><td>No cream No oil No sediment</td></tr><tr><td>Re-dispersion after 24 h</td><td>Complete</td><td>Complete</td></tr><tr><td>0.5 h after Re-dispersion</td><td>No cream No oil No sediment</td><td>No cream No oil No sediment</td></tr></table>	0.1 % w/v (at 25°C)				CIPAC A water	CIPAC D water	Initial Dispersion	Complete	Complete	0.5 h	No cream No oil No sediment	No cream No oil No sediment	Re-dispersion after 24 h	Complete	Complete	0.5 h after Re-dispersion	No cream No oil No sediment	No cream No oil No sediment	0.4 % w/v (at 25°C)				CIPAC A water	CIPAC D water	Initial Dispersion	Complete	Complete	0.5 h	No cream No oil No sediment	No cream No oil No sediment	Re-dispersion after 24 h	Complete	Complete	0.5 h after Re-dispersion	No cream No oil No sediment	No cream No oil No sediment	Y	Ravikumar M.A. 2021 VV-903874	Accepted.
0.1 % w/v (at 25°C)																																										
	CIPAC A water	CIPAC D water																																								
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Re-dispersion after 24 h	Complete	Complete																																								
0.5 h after Re-dispersion	No cream No oil No sediment	No cream No oil No sediment																																								
Degree of dissolution and dilution stability (KCP 2.8.4)	Not applicable as this is only required for water soluble formulations.					-																																				
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	Not applicable as this is not required for DC formulation.					-																																				
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	< 0.01% on a 75 µm sieve.	Y	Ravikumar M.A. 2021 VV-903873	Accepted.																																				
	CIPAC MT 185	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	< 0.01% on a 75 µm sieve.	Y	Ravikumar M.A. 2021 VV-903874	Accepted.																																				

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
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 required, formulation is not a powder or granule.			-
Attrition (KCP 2.8.5.3)			Not required, formulation is not a powder or granule.			-
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 not required for DC formulation.			-
Emulsion stability (KCP 2.8.6.2)			Not applicable as this is not required for DC formulation.			-
Re-emulsifiability (KCP 2.8.6.3)			Not applicable as this is not required for DC formulation.			-
Flowability (KCP 2.8.7.1)			Not applicable as this is only required for granular formulations.			-
Pourability (KCP 2.8.7.2)			Not applicable as this is not required for DC formulation.			-
Dustability following accelerated storage (KCP 2.8.7.3)			Not applicable as this is only required for dustable powders.			-
Physical compatibility of tank mixes (KCP 2.9.1)			Not applicable since it is not foreseen to mix the formulated product A23109A with other products.			-
Chemical compatibility of tank mixes (KCP 2.9.2)			Not applicable since it is not foreseen to mix the formulated product A23109A with other products.			-
Adhesion to seeds (KCP 2.10.1)			Not required, formulation is not used for seed treatment.			-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Distribution to seed (KCP 2.10.2)	Not required, formulation is not used for seed treatment.					-
Other/special studies (KCP 2.11)	CIPAC MT 30.6	Batch: JHU003-044-001 Oxathiapiprolin: 2.86 % w/w Metalaxyl-M: 16.9 % w/w	<u>Water content:</u> 3.14 % w/w	Y	Ravikumar M.A. 2021 VV-903866	Accepted.
	OPPTS 830.6314	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	<u>Chemical Compatibility:</u> Oxidizing Agent (5.3 – 7.9% sodium hypochlorite solution): Not Compatible Reducing Agent (Iron powder): Compatible Water (De-ionized): Not Compatible Fire Extinguishant (10% mono-ammonium phosphate solution): Not Compatible	Y	Jackson W. 2020a VV-903889	Accepted.
	Effectiveness Spray Tank Cleaning Procedure	Batch: JHU003-044-001 Oxathiapiprolin: 2.74 % w/w Metalaxyl-M: 16.4 % w/w	Tests have been carried out to determine the effectiveness of the tank cleaning procedure for A23109A (Oxathiapiprolin/Metalaxyl-M DC (030/180)). After applying the cleaning procedure, 0.06% residue was found in the refilled spray tank. The results show that the rising procedure sufficiently reduced the amount of residue in the spary tank.	Y	Breedt C. 2020 VV-903870	Accepted. Triple rinsing is recommended.
	Procedures for Cleaning Application Equipment	-	Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom and nozzles two to three times with clean water until the foam and all traces of the formulation have been removed.	N	Breedt. C. 2021 VV-903868	Accepted. Triple rinsing is recommended.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	Procedures for Destruction or Decontamination of the Plant Protection Product and its Packaging	-	<p><u>Neutralisation procedures for use in the event of accidental spillage</u></p> <p>In the event of accidental spillage, neutralisation (with acids or bases to neutral pH) is not an effective procedure for the destruction or decontamination of A23109A. Therefore, the spilled liquid formulation should first be absorbed onto a solid, such as sand, inert clay filler, saw dust or soil, before being swept up into a safe container to await disposal.</p> <p><u>Controlled incineration</u></p> <p>The halogen content of oxathiapiprolin, which is an active substance in the A23109A formulation, is 17.6 %. Metalaxyl-M, which is the second active substance in the A23109A formulation, has no halogen content.</p> <p>Conclusion: The halogen content of the active ingredients in the formulation is well below the 60 % limit. Therefore, the product A23109A can be disposed of safely by incineration in an incinerator, licensed to treat contaminated waste, which fulfils the following conditions: temperature at least 800°C, minimum residence time within the incinerator of 2 seconds and equipped with a washing unit for flue gases. The ashes have to be disposed of at a suitable, approved waste disposal site. The wash water has to be disposed of at a suitable, approved waste disposal site. The wash water has to be disposed of by means of a suitable waste water treatment plant.</p> <p><u>Disposal of Contaminated Packaging and Wastes</u></p> <p>The recommended method to dispose of contaminated packaging and waste is the incineration. Consult the supplier where bigger quantities have to be disposed of.</p>	N	Breedt C. 2021 VV-903869	Accepted.

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)

Comments of zRMS:	<p>The product showed no significant physical changes after accelerated storage. No significant changes were observed in the HDPE packaging and therefore it can be concluded that the test item was not corrosive to the container material.</p> <p>A storage stability study for 3y at ambient temperature has been initiated on 25th of September 2020 to demonstrate fitness for use up to 3 years.</p> <p>Results of a two-year storage stability study (HDPE, 1L) are available.</p> <p>The formulation is physically and chemically stable after storage for two years at 25°C in the high-density polyethylene HDPE packaging.</p>
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Table 4.1-1: Packaging information for 1 L canister

Type	Description	
Material:	High density polyethylene (HDPE)	
Shape/size:	Canister / diameter 89 mm, height 230 mm	Canister / diameter 92 mm, height 232 236 mm
Opening , closure and seal:	Screw cap closure (45 mm diameter) with induction heat seal or compression wad and tamper evident ring.	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring.
Manner of construction	Extruded	
UN/ADR	Compliant	

Table 4.1-2: Packaging information for 5 L canister

Type	Description	
Material:	High density polyethylene (HDPE)	
Shape/size:	Canister / 190 mm x 135 mm x 315 mm (Length x Width x Height)	Canister / 189 mm x 137 mm x 324 mm (Length x Width x Height)
Opening , closure and seal:	Screw cap closure (63 mm diameter) with induction heat seal or compression wad and tamper evident ring.	
Manner of construction	Extruded	
UN/ADR	Compliant	

The packaging for the product A23109A 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 CropLife International (formerly **GIFAP**) **Monograph 17**.

In line with the CropLife International (formerly **GIFAP**) **Monograph 17** latest edition (3rd edition from 2021, section 7.2.1)) additionally prolonged accelerated storage test data have been submitted, that are considered qualified to support an extended Shelf Life.

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 A23109A for up to 3 years under normal storage conditions.

A storage stability study was initiated on 25th of September 2020 to generate further supporting data to demonstrate fitness for use over an extended shelf life of 3 years.

For details please see Appendix 3.

Please refer to Registration Report Part A for any country specific packaging.

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	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Chemical Characterization Before Storage of Batch JHU003-044-001 Final Report Report No. SMG16480 Document No. VV-903866 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N/A	SYN
KCP 2.1	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physical and Technical Properties of Batch JHU003-044-001 Report No. SMG16481 Document No. VV-903873 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	SYN
KCP 2.2	Jackson, W.	13/11/2020	Oxathiapiprolin/Metalaxyl-M A23109A - Safety Study Final Report Report No. HT20/577 Document No. VV-903887 Test Facility Syngenta Limited GLP Unpublished	N	SYN
KCP 2.3	Jackson, W.	13/11/2020	Oxathiapiprolin/Metalaxyl-M A23109A - Safety Study Final Report Report No. HT20/577 Document No. VV-903887 Test Facility Syngenta Limited GLP Unpublished	N	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	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physico-Chemical Characteristics of Batch JHU003-044-001 Final Report Report No. SMG16482 Document No. VV-903874 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	SYN
KCP 2.4	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physical and Technical Properties of Batch JHU003-044-001 Report No. SMG16481 Document No. VV-903873 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	SYN
KCP 2.5	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physico-Chemical Characteristics of Batch JHU003-044-001 Final Report Report No. SMG16482 Document No. VV-903874 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	SYN
KCP 2.6	Breedt, C.	25/05/2021	Oxathiapiprolin/Metalaxyl-M A23109A - Storage Stability and Shelf Life Statement (2 Weeks and 4 Weeks 54 °C) in Packaging Made of HDPE According to CIPAC MT 46.4 Report No. 300185324 Document No. VV-903892 Test Facility Syngenta Crop Protection AG, GLP Testing Facility WMU Not GLP Unpublished	N	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 2.7	Breedt, C.	25/05/2021	Oxathiapiprolin/Metalaxyl-M A23109A - Storage Stability and Shelf Life Statement (2 Weeks and 4 Weeks 54 °C) in Packaging Made of HDPE According to CIPAC MT 46.4 Report No. 300185324 Document No. VV-903892 Test Facility Syngenta Crop Protection AG, GLP Testing Facility WMU Not GLP Unpublished	N	SYN
KCP 2.7	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physico-Chemical Characteristics of Batch JHU003-044-001 Final Report Report No. SMG16482 Document No. VV-903874 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	SYN
KCP 2.7	Breedt, C.	10/02/2023	Oxathiapiprolin/Metalaxyl-M A23109A - Storage Stability and Shelf Life Statement (2 Years 25 °C) in Packaging Made of HDPE Final Report Report No. 300224746 Document No. VV-982143 Test Facility Syngenta Crop Protection AG, GLP Testing Facility WMU Not GLP Unpublished	N	SYN
KCP 2.8.2	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physical and Technical Properties of Batch JHU003-044-001 Report No. SMG16481 Document No. VV-903873 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	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	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physical and Technical Properties of Batch JHU003-044-001 Report No. SMG16481 Document No. VV-903873 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	SYN
KCP 2.8.3	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physico-Chemical Characteristics of Batch JHU003-044-001 Final Report Report No. SMG16482 Document No. VV-903874 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	SYN
KCP 2.8.5.1	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physical and Technical Properties of Batch JHU003-044-001 Report No. SMG16481 Document No. VV-903873 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	SYN
KCP 2.8.5.1	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Physico-Chemical Characteristics of Batch JHU003-044-001 Final Report Report No. SMG16482 Document No. VV-903874 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	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 2.11	Breedt, C.	17/12/2020	A23109A – The Effectiveness of the Spray Tank Cleaning Procedure Report No. 450796 Document No. VV-903870 Test Facility Syngenta Crop Protection AG, GLP Testing Facility WMU Not GLP Unpublished	N	SYN
KCP 2.11	Breedt, C.	19/04/2021	A23109A Procedure for Cleaning Application Equipment Report No. N/A Document No. VV-903868 Test Facility N/A Not GLP Unpublished	N	SYN
KCP 2.11	Breedt, C.	19/04/2021	A23109A: Procedures for Destruction or Decontamination of the Plant Protection Product and its Packaging Report No. N/A Document No. VV-903869 Test Facility N/A Not GLP Unpublished	N	SYN
KCP 2.11	Jackson, W.	13/11/2020	Oxathiapiprolin/Metalaxyl-M A23109A - Oxidation/Reduction: Chemical Incompatibility Final Report Report No. HT20/578 Document No. VV-903889 Test Facility Syngenta Limited GLP Unpublished	N	SYN
KCP 2.11	Ravikumar, M.	01/04/2021	Oxathiapiprolin/Metalaxyl-M A23109A – Chemical Characterization Before Storage of Batch JHU003-044-001 Final Report Report No. SMG16480 Document No. VV-903866 Test Facility Syngenta Biosciences Pvt., Ltd. - GLP Testing Facility GOA GLP Unpublished	N	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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	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 Metalaxyl-M and Oxathiapiprolin.

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

Table A3-1: Content of active substances before and after storage at 54°C in HDPE packaging (VV-903892)

Active Substance	Initial	2 weeks		4 weeks	
		Control sample below -10°C	Test sample at 54°C	Control sample below -10°C	Test sample at 54°C
Oxathiapiprolin	2.86 % w/w Corresponding to 30.7 g/L	2.84 % w/w Corresponding to 30.5 g/L	2.84 % w/w Corresponding to 30.5 g/L	2.83 % w/w Corresponding to 30.4 g/L	2.81 % w/w Corresponding to 30.2 g/L
Metalaxyl-M Including its S-enantiomer	17.3 % w/w Corresponding to 186 g/L	17.2 % w/w Corresponding to 185 g/L	17.2 % w/w Corresponding to 185 g/L	17.1 % w/w Corresponding to 184 g/L	17.1 % w/w Corresponding to 184 g/L
Metalaxyl-M CGA329351 (R-enantiomer)	16.9 % w/w Corresponding to 182 g/L	16.8 % w/w Corresponding to 180 g/L	16.7 % w/w Corresponding to 179 g/L	16.6 % w/w Corresponding to 179 g/L	16.7 % w/w Corresponding to 178 g/L
CGA351920 (S-enantiomer)	0.445 % w/w Corresponding to 4.78 g/L	0.443 % w/w Corresponding to 4.76 g/L	0.456 % w/w Corresponding to 4.90 g/L	0.442 % w/w Corresponding to 4.75 g/L	0.467 % w/w Corresponding to 5.02g/L

Table A3-2: Physical and technical properties before and after storage at 54°C in HDPE packaging (VV-903892)

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C	Results after 4 weeks at 54 °C
Color	Visual	Brownish	Brownish	Brownish
Odor	Organoleptic	Slightly chemical odor	Slightly chemical odor	Slightly chemical odor
Physical State	Visual	Liquid	Liquid	Liquid
Appearance	Visual	Clear	Clear	Clear
pH Value Concentration: 1% Deionized Water	CIPAC MT 75.3	4.3	4.4	4.4
pH Value Undiluted	CIPAC MT 75.3	7.7	7.6	7.7
Relative Density Temperature: 20°C	OECD 109	1.074 g/cm ³	1.074 g/cm ³	1.074 g/cm ³
Wet Sieve Test Sieve size: 75 µm	CIPAC MT 185	< 0.01 %	< 0.01 %	< 0.01 %
Persistent Foaming Concentration: 0.1 % CIPAC water D	CIPAC MT 47.3	After 1 minute: 42 mL	After 1 minute: 46 mL	After 1 minute: 48 mL
Concentration: 0.4 % CIPAC water D		After 1 minute: 56 mL	After 1 minute: 58 mL	After 1 minute: 58 mL
Dispersion Stability Concentration: 0.1% CIPAC water A	CIPAC MT 180	Complete	Complete	Complete
Initial Dispersion Stability after 0.5 h - Initial top cream (or oil) - Initial sediment volume		No cream, no oil No sediment	No cream, no oil No sediment	No cream, no oil No sediment
Re-dispersion after 24 h		Complete	Complete	Complete
Stability 0.5 h after Re-dispersion - Top cream (or oil) - Sediment volume		No cream, no oil No Sediment	No cream, no oil No Sediment	No cream, no oil No Sediment

Test Description	Method	Initial Results	Results after 2 weeks at 54 °C	Results after 4 weeks at 54 °C
Dispersion Stability Concentration: 0.1% CIPAC water D Initial Dispersion Stability after 0.5 h - Initial top cream (or oil) - Initial sediment volume Re-dispersion after 24 h Stability 0.5 h after Re-dispersion - Top cream (or oil) - Sediment volume	CIPAC MT 180	Complete No cream, no oil No sediment Complete No cream, no oil No Sediment	Complete No cream, no oil No sediment Complete No cream, no oil No Sediment	Complete No cream, no oil No sediment Complete No cream, no oil No Sediment
Dispersion Stability Concentration: 0.4% CIPAC water A Initial Dispersion Stability after 0.5 h - Initial top cream (or oil) - Initial sediment volume Re-dispersion after 24 h Stability 0.5 h after Re-dispersion - Top cream (or oil) - Sediment volume	CIPAC MT 180	Complete No cream, no oil No sediment Complete No cream, no oil No Sediment	Complete No cream, no oil No sediment Complete No cream, no oil No Sediment	Complete No cream, no oil No sediment Complete No cream, no oil No Sediment
Dispersion Stability Concentration: 0.4% CIPAC water D Initial Dispersion Stability after 0.5 h - Initial top cream (or oil) - Initial sediment volume Re-dispersion after 24 h Stability 0.5 h after Re-dispersion - Top cream (or oil) - Sediment volume	CIPAC MT 180	Complete No cream, no oil No sediment Complete No cream, no oil No Sediment	Complete No cream, no oil No sediment Complete No cream, no oil No Sediment	Complete No cream, no oil No sediment Complete No cream, no oil No Sediment

Table A3-3: Packaging Evaluation after storage at 54°C in HDPE packaging (VV-903892)

Evaluation Criteria	Results after 2 weeks at 54 °C	Results after 4 weeks at 54 °C
Color change of the packaging	None	None
Odor (noticeable before opening the packaging)	None	None
Panelling of the test container	None	Weak
Ballooning of the test container	None	None
Pimples on the test container	None	None
Cracks in the test container	None	None
Tightness of the test container	Tight	Tight
Reclosability of closure	Reclosable	Reclosable
Tightness of closure	Tight	Tight
Weight change (gross weight)	0.01 % weight loss	0.02 % weight loss
Permeation through the container walls	None	None

The observed panelling had no adverse effect on the resistance of the packaging material, since the pack and the closure were found to be tight.

Appendix 4 Storage stability data before and after storage over 2 years at 25°C in HDPE packaging

Table A4-1: Content of active substances before and after storage over 2 years at 25°C in HDPE packaging (VV-982143)

Active Ingredient	Initial	2 years below -10 °C (control sample)	2 years 25 °C (test sample)
oxathiapiprolin	2.86 % w/w corresponding to 30.7 g/l	2.81 % w/w corresponding to 30.2 g/l	2.79 % w/w corresponding to 30.0 g/l
metalaxyl-M including its S-enantiomer	17.3 % w/w corresponding to 186 g/l	17.0 % w/w corresponding to 183 g/l	16.9 % w/w corresponding to 182 g/l
Metalaxyl-M CGA329351 (R-enantiomer)	16.9 % w/w corresponding to 182 g/l	16.6 % w/w corresponding to 178 g/l	16.4 % w/w corresponding to 176 g/l
CGA351920 (S-enantiomer)	0.445 % w/w corresponding to 4.78 g/l	0.448 % w/w corresponding to 4.81 g/l	0.454 % w/w corresponding to 4.88 g/l

Observations and Conclusion

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

Table A4-2: Physical and technical properties before and after storage over 2 years at 25°C in HDPE packaging (VV-982143)

Test Description	Method	Initial Results	Results after 2 years 25 °C
Color	Visual	brownish	brownish
Odor	Organoleptic	slightly chemical odor	slightly chemical odor
Physical State	Visual	liquid	liquid
Appearance	Visual	clear	clear
pH Value Concentration: 1 % Deionized Water	CIPAC MT 75.3	4.3	4.7
pH Value Undiluted	CIPAC MT 75.3	7.7	7.3
Persistent Foaming CIPAC Water D Waiting Period: 1 min Concentration: 0.4 % Concentration: 0.1 %	CIPAC MT 47.3	56 ml 42 ml	56 ml 52 ml
Density Temperature: 20 °C	OECD 109	1.074 g/cm ³	1.075 g/cm ³
Wet Sieve Test Sieve Size: 75 µm	CIPAC MT 185	< 0.01 %	< 0.01 %

Test Description	Method	Initial Results	Results after 2 years 25 °C
Dispersion Stability Concentration: 0.4 % CIPAC Water A Initial Dispersion Stability after 0.5 h - Initial Top Cream (or Oil) - Initial Sediment Volume Re-dispersion after 24 h Stability 0.5 h after Re-dispersion - Top Cream (or Oil) - Sediment Volume	CIPAC MT 180	complete no cream, no oil no sediment complete no cream, no oil no sediment	complete no cream, no oil no sediment complete no cream, no oil no sediment
Dispersion Stability Concentration: 0.4 % CIPAC Water D Initial Dispersion Stability after 0.5 h - Initial Top Cream (or Oil) - Initial Sediment Volume Re-dispersion after 24 h Stability 0.5 h after Re-dispersion - Top Cream (or Oil) - Sediment Volume	CIPAC MT 180	complete no cream, no oil no sediment complete no cream, no oil no sediment	complete no cream, no oil no sediment complete no cream, no oil no sediment
Dispersion Stability Concentration: 0.1 % CIPAC Water A Initial Dispersion Stability after 0.5 h - Initial Top Cream (or Oil) - Initial Sediment Volume Re-dispersion after 24 h Stability 0.5 h after Re-dispersion - Top Cream (or Oil) - Sediment Volume	CIPAC MT 180	complete no cream, no oil no sediment complete no cream, no oil no sediment	complete no cream, no oil no sediment complete no cream, no oil no sediment
Dispersion Stability Concentration: 0.1 % CIPAC Water D Initial Dispersion Stability after 0.5 h - Initial Top Cream (or Oil) - Initial Sediment Volume Re-dispersion after 24 h Stability 0.5 h after Re-dispersion - Top Cream (or Oil) - Sediment Volume	CIPAC MT 180	complete no cream, no oil no sediment complete no cream, no oil no sediment	complete no cream, no oil no sediment complete no cream, no oil no sediment

Observations and Conclusion

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

Table A4-3: Packaging Evaluation storage over 2 years at 25°C in HDPE packaging (VV-982143)

Evaluation Criteria	Results after 2 years 25 °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)	0.03 % weight loss
Permeation through the container walls	none

Observations and Conclusion

The packaging material proved to be resistant to its content.