

# 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: GF-3307 (S7K-3-3)

Product name(s): QUEEN

Chemical active substances:

Fenpicoxamid (XDE-777), 50 g/L

Prothioconazole, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

## CORE ASSESSMENT

(extension of use)

Applicant: Corteva Agriscience

Submission date: March 2025

MS Finalisation date: August 2025 (initial Core Assessment)

November 2025 (final Core Assessment)

### Version history

When	What
March 2025	Submission of GF-3307 (S7K-3-3) Sugar beet/Fodder beet Extension of Use in the Central Zone.
August 2025	<p>Initial zRMS assessment</p> <p>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 <del>struck through</del> and shaded for transparency.</p>
November 2025	<p>Final report (Core Assessment updated following the commenting period)</p> <p>No additional information or assessments after the commenting period.</p>

## Table of Contents

<b>1</b>	<b>Section 1: Identity of the plant protection product .....</b>	<b>4</b>
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 Producer(s) of the active substance(s) .....	4
1.2.4	Statement of purity (and detailed information on impurities) of the active substance(s) .....	4
1.2.4.1	Active substance Fenpicoxamid .....	4
1.2.4.2	Active substance Prothioconazole .....	4
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).....	5
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
<b>2</b>	<b>Section 2: Physical, chemical and technical properties of the plant protection product.....</b>	<b>7</b>
<b>3</b>	<b>Section 3 is presented as a separate document.....</b>	<b>20</b>
<b>4</b>	<b>Section 4: Further information on the plant protection product .....</b>	<b>21</b>
4.1	Packaging and Compatibility with the Preparation (KCP 4.4).....	21
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation.....</b>	<b>23</b>

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).

Noticed data gaps are: none.

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

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

Central Address	-
Telephone	-
Contact	-
Email	-
Member State Address	-
Telephone	-
Contact	-
Email	-

### **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 or data are provided separately (Part C).

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

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

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

##### **1.2.4.1 Fenpicoxamid**

End-Point	Fenpicoxamid (XDE-777)
Reference	Commission Implementing Regulation 2018/1265
Purity of active substance	> 750 g/kg

There are no relevant impurities in active substance, Fenpicoxamid. Information relating to the impurities is confidential information; please refer to Part C (confidential information).

##### **1.2.4.2 Prothioconazole**

End-Point	Prothioconazole
Reference	Commission Implementing Regulation (EU) No 540/2011

Purity of active substance	> 970 g/kg
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The following manufacturing impurities are of toxicological concern and each of them must not exceed a certain amount in the technical material:

- Toluene: < 5 g/kg
- Prothioconazole-desthio(2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol): < 0,5 g/kg (LOD)

Information relating to the impurities is confidential information; please refer to Part C (confidential information).

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

Trade name: QUEEN

Company code number: GF-3307 (S7K-3-3)

### 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)

GF-3307 was not the representative formulation in the active substance approval.

**Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)**

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L)	Technical content** (%w/w)
Fenpicoxamid	50.0	45.0 – 55.0	66.7	6.39
Prothioconazole	100.0	90.0 – 110.0	103.0	9.88

\* Based on minimum technical purities of 750 g/kg for Fenpicoxamid and 970 g/kg for Prothioconazole

\*\* Based on the density of the formulation = 1.044 g/mL

**Table 1.4-2: Safener and synergists**

Safener / synergist	Declared content of the safener / synergist (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
N/A	N/A	N/A	N/A	N/A

**Table 1.4-3: Relevant impurities**

Relevant impurity	Maximum content (g/kg)
Prothioconazole-desthio	< 0.5
Toluene	< 5

## 1.4.2 Information on the active substance(s) (KCP 1.4.2)

**Table 1.4-4: Information on the active substance Fenpicoxamid**

Type	Name/Code Number
ISO common name	Fenpicoxamid
CAS No.	517875-34-2
EC No.	Not available
CIPAC No.	991

**Table 1.4-5: Information on the active substance Prothioconazole**

Type	Name/Code Number
ISO common name	Prothioconazole
CAS No.	178928-70-6
EC No.	605-841-2
CIPAC No.	745

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

This product does not contain safeners or synergists.  
CONFIDENTIAL information is provided separately (Part C).

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

Type: Emulsion concentrate

[Code: EC]

## 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 orange liquid (19.7 °C), with a fruity odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of 76.5 °C. It has a self-ignition temperature of 368 °C. In aqueous solution, it has a pH value around 4.60 at 21.6 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C, 14 days at 54 °C, and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The product showed > 5% degradation of fenpicoxamid in 1-L COEX (HDPE/PA), 1-L F-HDPE, and 25-L steel after 2 years in ambient storage conditions but all breakdown products were identified and acceptable mass balance was demonstrated. The technical characteristics of GF-3307 are acceptable for an emulsifiable concentrate formulation.

The intended concentration of use is 0.5% to 1.0% per application.

Comments of zRMS:	The final version of the report was prepared in February 2023 (please refer final report - Core Assessment updated following the commenting period). No new studies have been presented for the purpose of extension of use, and all studies presented in the version of the report "February 2023" are still accepted. The intended concentration of use is 0.5% to 1.0% per application is supported by existing studies.
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### Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

No classification is required by the physical and chemical properties of GF-3307.

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

No risk and safety phrases are required by the physical and chemical properties of GF-3307.

### Compliance with FAO specifications:

The product GF-3307 complies with FAO specifications.

### Formulation used for tests

The product, GF-3307, that was used in the tests has the same composition as what was cited in the Part C.

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

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	Visual and Olfactory Inspection	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	Orange liquid at 19.7 °C, fruity	Y	FAPC-G-15-36, Moe, T., Julien, T.	Accepted.
Explosive properties (KCP 2.2.1)	EEC A14	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	Not Explosive	Y	NAFST-15-159, Dunning, J.	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.
Oxidizing properties (KCP 2.2.2)	EEC A21	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	Non-oxidizing:	Y	NAFST-15-159, Dunning, J.	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.
Flash point (KCP 2.3.1)	CIPAC MT 12.3 EEC A9	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	A flash point was observed at 76.5 °C	Y	FAPC-G-15-36, Moe, T., Julien, T.	Accepted.  The formulation is not flammable. The formulation does not need to be classified according to Reg. (EC)



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						1272/2008, in line with the tests/requirements in the UN-RTDG manual.
Flammability (KCP 2.3.2)	EEC A10	-	Refer to 2.3.1	-	-	-
Self-heating (KCP 2.3.3)	EEC A15	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	None. Below 400°C	Y	NAFST-15-159, Dunning, J.	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.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 75.3	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	4.78 (21.9 °C) on 1% w/v preparation	Y	FOR-14-35, Hofer, C.	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT75.3	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	1% wt/wt aqueous solution was 4.60 at 21.6 °C	Y	FAPC-G-15-36, Moe, T., Julien, T.	Accepted.
Viscosity (KCP 2.5.1)	OECD 114 CIPAC MT 22.3	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	Newtonian formulation with a viscosity of 16.3 mPa•s at 20.0 °C and 8.79 mPa•s at 40.0 °C  Kinematic viscosity (mm <sup>2</sup> /s) = Dynamic viscosity (mPa s) / Density (g/cm <sup>3</sup> ) = 16.3 mPa•s / 1.0389 g/cm <sup>3</sup> = 15.69 mm <sup>2</sup> /s at 20.0 °C Kinematic viscosity (mm <sup>2</sup> /s) = Dynamic viscosity (mPa s) / Density (g/cm <sup>3</sup> ) = 8.79 mPa•s / 1.0389 g/cm <sup>3</sup> = 8.46 mm <sup>2</sup> /s at 40.0 °C	Y	FAPC-G-15-36, Moe, T., Julien, T.	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Results are below the trigger value of 20.5 mm <sup>2</sup> /s. The formulation contains no hydrocarbons or co-formulants classified with H304. Hence GF-3307 should not be classified for aspiration hazard.			
Surface tension (KCP 2.5.2)	EEC A5	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	Neat at 25 °C 28.5 mN/m Neat at 40 °C 27.5 mN/m 2% v/v dilution at 20 °C 26.5 mN/m	Y	NAFST-15-159, Dunning, J.	Accepted.  The formulation is surface active.
Relative density (KCP 2.6.1)	EEC A3	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	1.0389 g/mL at 20 °C.	Y	FAPC-G-15-36, Moe, T., Julien, T.	Accepted.
Bulk density (KCP 2.6.2)	CIPAC MT 186	-	Not Applicable, Formulation is an EC	-	-	-
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole  TSN314279 4.7% Fenpicoxamid, 9.3% Prothioconazole	Based on the chemical and physical results obtained from the study, it can be concluded that GF-3307 is chemically and/or physically stable in 1-L COEX (HDPE/PA) and 1-L F-HDPE after 14 days at 54 °C storage conditions.  Fenpicoxamide content: T = 0 : 4.79 wt/wt% T = 2 weeks in HDPEf: 4.61 wt/wt%; -3.8% T = 2 weeks in COEX (HDPE/PA): 4.59 wt/wt%; -4.2% <5% relative change  Prothioconazole content: T = 0 : 9.59 wt/wt% T = 2 weeks in HDPEf: 9.54 wt/wt%; -0.5% T = 2 weeks in COEX (HDPE/PA): 9.51 wt/wt%; -0.8% <5% relative change  Desthio impurity content: T = 0 : <LOQ T = 2 weeks in HDPEf: <LOQ T = 2 weeks in COEX (HDPE/PA): <LOQ LOQ = 19ppm. This LOQ is in accordance with the maximum allowable limit for desthio	Y	FOR-14-35, Hofer, C	The product showed no significant physical changes after accelerated storage.  No significant changes were observed in the, HDPE/PA and HDPE/F packaging and therefore it can be concluded that the test item was not corrosive to the container material.  The accelerated stability data indicate a shelf life of at least 2 years at ambient

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																								
			<p>impurity.</p> <p>Appearance: No significant change in both packaging Packaging observations: No significant change in both packaging</p> <table><tr><th>Test</th><th>Time Zero</th><th>Two Weeks 54°C in COEX</th><th>Two Weeks 54°C in F-HDPE</th><th>Low Temperature (One Week 0°C in Glass)</th></tr><tr><td>pH 1% w/v</td><td>4.78 at 21.9°C</td><td>4.72 at 21.9°C</td><td>4.72 at 21.8°C</td><td>N/A</td></tr><tr><td>Persistent Foam, 2.1% w/v (mL)</td><td></td><td></td><td></td><td></td></tr><tr><td>10 sec</td><td>53</td><td>40</td><td>41</td><td></td></tr><tr><td>1 min</td><td>14</td><td>12</td><td>13</td><td></td></tr><tr><td>3 min</td><td>6</td><td>4</td><td>3</td><td></td></tr><tr><td>12 min</td><td>4</td><td>3</td><td>3</td><td></td></tr><tr><td>Emulsion Stability* 2.0% w/v and 0.67% v/v GF-3307 in Standard Water A and D</td><td colspan="4">Results were trace cream or oil after 30 minutes and ≤ 0.2 mL cream and no oil after 2 hours in standard water A and D before and after two weeks of storage at 54°C in COEX and F-HDPE and before and after one week of storage at 0°C in glass.</td></tr></table>	Test	Time Zero	Two Weeks 54°C in COEX	Two Weeks 54°C in F-HDPE	Low Temperature (One Week 0°C in Glass)	pH 1% w/v	4.78 at 21.9°C	4.72 at 21.9°C	4.72 at 21.8°C	N/A	Persistent Foam, 2.1% w/v (mL)					10 sec	53	40	41		1 min	14	12	13		3 min	6	4	3		12 min	4	3	3		Emulsion Stability* 2.0% w/v and 0.67% v/v GF-3307 in Standard Water A and D	Results were trace cream or oil after 30 minutes and ≤ 0.2 mL cream and no oil after 2 hours in standard water A and D before and after two weeks of storage at 54°C in COEX and F-HDPE and before and after one week of storage at 0°C in glass.						temperature when stored in HDPE/PA and HDPE/F.
Test	Time Zero	Two Weeks 54°C in COEX	Two Weeks 54°C in F-HDPE	Low Temperature (One Week 0°C in Glass)																																										
pH 1% w/v	4.78 at 21.9°C	4.72 at 21.9°C	4.72 at 21.8°C	N/A																																										
Persistent Foam, 2.1% w/v (mL)																																														
10 sec	53	40	41																																											
1 min	14	12	13																																											
3 min	6	4	3																																											
12 min	4	3	3																																											
Emulsion Stability* 2.0% w/v and 0.67% v/v GF-3307 in Standard Water A and D	Results were trace cream or oil after 30 minutes and ≤ 0.2 mL cream and no oil after 2 hours in standard water A and D before and after two weeks of storage at 54°C in COEX and F-HDPE and before and after one week of storage at 0°C in glass.																																													
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	CIPAC MT 46.3	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	<p>Based on the chemical and physical results obtained from the study, it can be concluded that GF-3307 is chemically and/or physically stable in 1-L COEX (HDPE/PA) and 1-L F-HDPE after 8 weeks at 40 °C storage conditions.</p> <p><u>Fenpicoxamide content:</u> T = 0 : 4.79 wt/wt% T = 8 weeks in HDPEf: 4.58 wt/wt%; -4.4% T = 8 weeks in COEX (HDPE/PA): 4.60 wt/wt%; -4.0% &lt;5% relative change</p> <p><u>Prothioconazole content:</u> T = 0 : 9.59 wt/wt% T = 8 weeks in HDPEf: 9.38 wt/wt%; -2.2% T = 8 weeks in COEX (HDPE/PA): 9.41 wt/wt%; -1.9% &lt;5% relative change</p>	Y	FOR-14-36, Hofer, C	<p>No significant changes were observed in the, HDPE/PA and HDPE/F packaging and therefore it can be concluded that the test item was not corrosive to the container material.</p> <p>The accelerated stability data indicate a shelf life of at least 2 years at ambient</p>																																								

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																								
			<p><u>Desthio impurity content:</u> T = 0 : &lt;LOQ T = 8 weeks in HDPEf: &lt;LOQ T = 8 weeks in COEX (HDPE/PA): 17 ppm</p> <p><u>Appearance:</u> No significant change in both packaging</p> <p><u>Packaging observations:</u> No significant change in both packaging</p> <table><tr><th>Test</th><th>Time Zero</th><th>Eight Weeks 40°C in COEX</th><th>Eight Weeks 40°C in F-HDPE</th><th>Eight Weeks 40°C in Steel</th></tr><tr><td>pH 1% w/v</td><td>4.78 at 21.9°C</td><td>4.73 at 23.1°C</td><td>4.66 at 23.2°C</td><td>4.61 at 23.2°C</td></tr><tr><td>Persistent Foam, 2.1% w/v (mL)</td><td></td><td></td><td></td><td></td></tr><tr><td>10 sec</td><td>53</td><td>38</td><td>35</td><td>43</td></tr><tr><td>1 min</td><td>14</td><td>12</td><td>11</td><td>10</td></tr><tr><td>3 min</td><td>6</td><td>1</td><td>1</td><td>1</td></tr><tr><td>12 min</td><td>4</td><td>1</td><td>1</td><td>1</td></tr><tr><td>Emulsion Stability* 2.0% w/v and 0.67% w/v GF-3307 in Standard Water A and D</td><td colspan="4">Results were trace cream or no cream and no oil after 30 minutes. After two hours there was ≤ 0.15 mL cream and no oil in standard water A and D before and after eight weeks of storage at 40°C in COEX, F-HDPE and steel.</td></tr></table>	Test	Time Zero	Eight Weeks 40°C in COEX	Eight Weeks 40°C in F-HDPE	Eight Weeks 40°C in Steel	pH 1% w/v	4.78 at 21.9°C	4.73 at 23.1°C	4.66 at 23.2°C	4.61 at 23.2°C	Persistent Foam, 2.1% w/v (mL)					10 sec	53	38	35	43	1 min	14	12	11	10	3 min	6	1	1	1	12 min	4	1	1	1	Emulsion Stability* 2.0% w/v and 0.67% w/v GF-3307 in Standard Water A and D	Results were trace cream or no cream and no oil after 30 minutes. After two hours there was ≤ 0.15 mL cream and no oil in standard water A and D before and after eight weeks of storage at 40°C in COEX, F-HDPE and steel.						temperature when stored in HDPE/PA and HDPE/F.
Test	Time Zero	Eight Weeks 40°C in COEX	Eight Weeks 40°C in F-HDPE	Eight Weeks 40°C in Steel																																										
pH 1% w/v	4.78 at 21.9°C	4.73 at 23.1°C	4.66 at 23.2°C	4.61 at 23.2°C																																										
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3 min	6	1	1	1																																										
12 min	4	1	1	1																																										
Emulsion Stability* 2.0% w/v and 0.67% w/v GF-3307 in Standard Water A and D	Results were trace cream or no cream and no oil after 30 minutes. After two hours there was ≤ 0.15 mL cream and no oil in standard water A and D before and after eight weeks of storage at 40°C in COEX, F-HDPE and steel.																																													
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Refer to 2.7.1	-	-	-																																								
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	No significant physical changes and all performance properties were within acceptable limits.	Y	FOR-14-35, Hofer, C	Accepted.																																								
Ambient temperature shelf life (KCP 2.7.5)	CIPAC MT 46.3	TSN309374 4.80% Fenpicoxamid, 9.59%	Prothioconazole in GF-3307 is chemically and physically stable in COEX (HDPE/PA), F-HDPE, and steel through two years of warehouse ambient storage. Fenpicoxamid showed loss > 5% in COEX (HDPE/PA), F-HDPE, and steel through two years of warehouse ambient storage. Breakdown products were quantitated and acceptable mass balance was	Y	FOR-14-37, Hofer, C	Study accepted.  The HDPE/PA, F-HDPE and steel																																								

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																					
		Prothioconazole  Ai content: Method DAS-AM-G-14-24  Desthio content: Method DAS-AM-G-14-38  X12393285: Method DAS-AM-G-14-35  X12335723: Method DAS-AM-G-15-1  X12314005: Method DAS-AM-G-170058	<div>demonstrated. The total mass balance of fenpicoxamid and its breakdown products was ≥ 98.6% in COEX (HDPE/PA), F-HDPE, and steel through two years of warehouse ambient storage. All performance properties remained within specifications.</div> <table><thead><tr><th>Test</th><th>Method Reference</th><th>Findings</th></tr></thead><tbody><tr><td>Active Ingredient Content</td><td>DAS-AM-G-14-24</td><td>Prothioconazole content remained chemically stable after two years of storage at warehouse ambient conditions in COEX, F-HDPE, and steel (&lt; 5% change from time zero analysis). Fenpicoxamid content changed &gt; 5% after two years of storage at warehouse ambient conditions in COEX, F-HDPE, and steel.</td></tr><tr><td>Potential Degradants</td><td>DAS-AM-G-14-35 DAS-AM-G-15-1 DAS-AM-G-170058</td><td>Potential degradants of X12393285, X12335723, and X12314005 were quantitated and acceptable total mass balance was demonstrated.</td></tr><tr><td>Relevant Impurity Content</td><td>DAS-AM-G-14-38</td><td>Desthio impurity remained within specifications after two years of storage at warehouse ambient conditions in F-HDPE, COEX, and steel (Content &lt; 50 ppm).</td></tr><tr><td>Appearance</td><td>N/A</td><td>Product showed no significant physical changes after two years of storage at warehouse ambient conditions in F-HDPE, COEX, and steel. Throughout two years of storage the product remained a clear orange or clear amber liquid. It was noted that the test substance in steel was a darker shade than F-HDPE or COEX.</td></tr><tr><td>Packaging Assessment</td><td>N/A</td><td>A slight odor was noted after 18 months in F-HDPE and COEX bottles. No odor was noted in F-HDPE, COEX, and steel containers after two years of warehouse ambient storage. F-HDPE and COEX containers showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product after two years of storage at warehouse ambient conditions. There was corrosion at the top of the two year steel container but was determined to be due to environmental conditions of warehouse ambient storage and not due to the test substance compatibility with the steel container.</td></tr><tr><td>pH (1% w/v)</td><td>CIPAC MT 75.3</td><td>Time Zero - 4.78 at 21.9°C Two Years in Steel - 4.60 at 19.3°C Two Years in F-HDPE - 4.59 at 19.4°C Two Years in COEX - 4.54 at 19.9°C</td></tr><tr><td>Persistent Foam</td><td>CIPAC MT 47.2</td><td>Results were ≤ 60 mL foam after 1 minute at 2.1% w/v before and after two years of storage at warehouse ambient conditions in COEX, F-HDPE, and steel.</td></tr><tr><td>Emulsion Stability</td><td>CIPAC MT 36.3</td><td>Results were ≤ 2 mL of cream after 30 minutes and no oil at 2.0% v/v and 0.67% v/v in standard water A and D before and after two years of storage at warehouse ambient conditions in COEX, F-HDPE, and steel.</td></tr></tbody></table> <div>The 30-month storage stability data (reference FOR-171251) of GF-3307 in COEX (HDPE/PA) and F-HDPE is already available:</div> <table><thead><tr><th>Method used</th><th>Test Material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th></tr></thead><tbody><tr><td>CIPAC MT 46.3</td><td>TSN309374 9.59 % wt Prothioconazole 4.80 % wt Fenpicoxamid</td><td>Prothioconazole in GF-3307 is chemically and physically stable in COEX, F-HDPE, and steel through 30 months of warehouse</td><td>Y</td><td>FOR-171251</td></tr></tbody></table>	Test	Method Reference	Findings	Active Ingredient Content	DAS-AM-G-14-24	Prothioconazole content remained chemically stable after two years of storage at warehouse ambient conditions in COEX, F-HDPE, and steel (< 5% change from time zero analysis). Fenpicoxamid content changed > 5% after two years of storage at warehouse ambient conditions in COEX, F-HDPE, and steel.	Potential Degradants	DAS-AM-G-14-35 DAS-AM-G-15-1 DAS-AM-G-170058	Potential degradants of X12393285, X12335723, and X12314005 were quantitated and acceptable total mass balance was demonstrated.	Relevant Impurity Content	DAS-AM-G-14-38	Desthio impurity remained within specifications after two years of storage at warehouse ambient conditions in F-HDPE, COEX, and steel (Content < 50 ppm).	Appearance	N/A	Product showed no significant physical changes after two years of storage at warehouse ambient conditions in F-HDPE, COEX, and steel. Throughout two years of storage the product remained a clear orange or clear amber liquid. It was noted that the test substance in steel was a darker shade than F-HDPE or COEX.	Packaging Assessment	N/A	A slight odor was noted after 18 months in F-HDPE and COEX bottles. 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Data on validation of breakdown products and relevant impurities are available in Section B5  Period of validity: 2 years.
Test	Method Reference	Findings																																									
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Annex point	Method used / deviations	Test material	Findings				GLP Y/N	Reference	Acceptability / comments
					<p>ambient storage. Fenpicoxamid showed a loss &gt; 5% in COEX, F-HDPE, and steel containers through 30 months of warehouse ambient storage. Breakdown products of X12393285, X12335723, and X12314005 were quantitated and acceptable mass balance (<math>\geq 98\%</math>) was demonstrated. The total mass balance of fenpicoxamid and its breakdown products was <math>\geq 98\%</math> in COEX, F-HDPE, and steel through 30 months of warehouse ambient storage. The F-HDPE and steel packaging were stable after storage whereas an increase of desthio content in COEX was observed after storage. All performance test properties remained within specifications.</p>				
			<b>Stability of Active Ingredients in GF-3307</b>						

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																																																																								
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Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	-	-	Not Relevant	-																																																																						
Wettability (KCP 2.8.1)	-	-	Not required for EC formulations	-	Not Relevant	-																																																																						
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.2	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	All foam measurements were within acceptable limits (≤ 60 mL foam in Standard water D.) <u>2.1% w/v:</u> t = 10s: 53 mL t = 1min: 14 mL t = 3 min: 6 mL t = 12 min: 4 mL	Y	FOR-14-37, Hofer, C	Accepted.																																																																						
Suspensibility (KCP 2.8.3.1)	-	-	Not required for EC formulations	-	Not Relevant	-																																																																						



Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Spontaneity of dispersion (KCP 2.8.3.2)	-	-	Not required for EC formulations	-	Not Relevant	-
Dispersion stability (KCP 2.8.3.3)	-	-	Not required for EC formulations	-	Not Relevant	-
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required for EC formulations	-	Not Relevant	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not required for EC formulations	-	Not Relevant	-
Wet sieve test (KCP 2.8.5.1.2)	-	-	Not required for EC formulations	-	Not Relevant	-
Dust content (KCP 2.8.5.2.1)	-	-	Not required for EC formulations	-	Not Relevant	-
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for EC formulations	-	Not Relevant	-
Attrition (KCP 2.8.5.3)	-	-	Not required for EC formulations	-	Not Relevant	-
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for EC formulations	-	Not Relevant	-
Emulsifiability (KCP 2.8.6.1)	CIPAC MT 36.3	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	Refer to 2.8.6.2	Y	FOR-14-37, Hofer, C	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Emulsion stability (KCP 2.8.6.2)	CIPAC MT 36.3	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole  TSN314279 4.7% Fenpicoxamid, 9.3% Prothioconazole	Results for 0.67% v/v and 2.0% v/v - 2 year ambient in 1-L COEX and 1-L F-HDPE: All emulsion measurements were within acceptable limits ( $\leq 2$ mL cream after 30 minutes in Standard waters A and D.)  Results for 0.4% v/v - 2 week at 54°C in 1-L COEX and 1-L F-HDPE: All emulsion measurements were within acceptable limits ( $\leq 2$ mL cream after 30 minutes in Standard waters A and D.)	Y  Y	FOR-14-37, Hofer, C  FOR-180883, Stoltz V.	Accepted.
Re-emulsifiability (KCP 2.8.6.3)	CIPAC MT 36.3	TSN309374 4.80% Fenpicoxamid, 9.59% Prothioconazole	Refer to 2.8.6.2	Y	FOR-14-37, Hofer, C	Refer to 2.8.6.2
Flowability (KCP 2.8.7.1)	-	-	Not required for EC formulations	-	Not Relevant	-
Pourability (KCP 2.8.7.2)	-	-	Not required for EC formulations	-	Not Relevant	-
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not required for EC formulations	-	Not Relevant	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not required for EC formulations	-	Not Relevant	-
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not required for EC formulations	-	Not Relevant	-
Adhesion to seeds	-	-	Not required for EC formulations	-	Not Relevant	-

Annex point	Method used / deviations	Test material	Findings						GLP Y/N	Reference	Acceptability / comments
(KCP 2.10.1)											
Distribution to seed (KCP 2.10.2)	-	-	Not required for EC formulations						-	Not Relevant	-
Other/special studies (KCP 2.11)	Amega Sciences methods	GF-3307	With a single rinse with water at an amount of 10% of the spray tank volume, GF-3307 can be removed by 99.9% from sprayer surfaces which is considered an excellent result.						-	LES 10126, Topham, D,	Accepted. Triple rinse is recommended.
			Fungicide Formulation	Active Concentration (total) (ppm)/Part (mg) in test tank	Parts (mg) retained without washing	% removed without cleaning	Parts (mg) retained after washing with 10% tank volume water	% Removed after 10% tank volume water used to wash			
			GF-2925	650ppm/97.5mg	0.1703	99.8253	0.0534	99.9452			
			GF-3307	1500ppm/225mg	0.0628	99.9720	0.0086	99.9691			
			GF-3308	500ppm/75mg	0.0724	99.9903	0.0277	99.9630			
			GF-3309	1125ppm/168.75mg	0.0596	99.9646	0.0134	99.9920			
			GF-3521	1000ppm/150mg	0.0615	99.9590	0.0148	99.9901			

### **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:	The accelerated stability data and ambient temperature storage stability data indicate a shelf life of at least 2 years when stored in HDPE/PA, HDPE-F and steel containers.
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**Table 4.1-1: Packaging information for 0.25 – 60 litre F-HDPE bottle/jerrican/drum**

Type	Description
Material:	F-HDPE
Shape/size:	Bottles/Jerrican for 0.25 litre, 0.5 litre, 1 litre, 2 litre, 3 litre, 5 litre, 7.5 litre, 10 litre, 15 litre, 20 litre. 0.25 litre bottles may or may not be packed 20 x 0.25 litre to an outer corrugated fibreboard case. 0.5 litre bottles, may or may not be, packed 20 x 0.5 litre to an outer corrugated fibreboard case. 1 litre bottles, may or may not be, packed 10 x 1 litre or 12 x 1 litre to an outer corrugated fibreboard case. 2 litre bottles, may or may not be, packed 8 x 2 litre to an outer corrugated fibreboard case. 3 litre bottles, may or may not be, packed 6 x 3 litre to an outer corrugated fibreboard case. 5 litre bottles, may or may not be, packed 2 x 5 litre, 3 x 5 litre or 4 x 5 litre to an outer corrugated fibreboard case 7.5 litre bottles, may or may not be, packed 2 x 7.5 litre to an outer corrugated fibreboard case 10 litre jerrican may or may not be, packed 2 x 10 litre to an outer corrugated fibreboard case. 15 litre jerrican, may or may not be, packed 2x15litre to an outer corrugated fibreboard case 20 litre jerrican may or may not be packed to an outer corrugated fibreboard case. 60 litre drum
Opening:	28, 45, 50, 57.7, 60, 61 and 63 mm inner diameter
Closure:	Screw cap 28mm – for 1L bottles 45mm – from 0.25L up to 2L bottles 50mm – from 0.25L up to 2L bottles 57.7 mm – for 60L drum 60mm – for 15L and 20L jerricans 61mm – for 15L and 20L jerricans 63mm – for 3L, 5L, 7.5L, 10L, 15L and 20L bottles/jerricans
Seal:	Induction, compression or vented
Manner of construction	Extruded
UN/ADR	Compliant
Refillable or returnable	No

**Table 4.1-2: Packaging information for 0.1 – 20 liter COEX HDPE/PA bottle/jerrican**

Type	Description
Material:	COEX HDPE/PA (external material HDPE / inner barrier Polyamide)
Shape/size:	Bottles/Jerrican for 0.1 litre, 0.5 litre, 1 litre, 2 litre, 3 litre, 5 litre, 5.2 litre, 6.2 litre, 7 litre, 7.5 litre, 10 litre, 15 litre, 20 litre. 0.1 litre bottles may or may not be packed 30 x 0.1 litre to an outer corrugated fibreboard case. 0.5 litre bottles, may or may not be, packed 10 x 0.5 litre or 20 x 0.5 litre to an outer corrugated fibreboard case. 1 litre bottles, may or may not be, packed 10 x 1 litre to an outer corrugated fibreboard case. 2 litre bottles, may or may not be, packed 8 x 2 litre to an outer corrugated fibreboard case. 3 litre bottles, may or may not be, packed 6 x 3 litre to an outer corrugated fibreboard case. 5 litre bottles, may or may not be, packed 2 x 5 litre, 3 x 5 litre or 4 x 5 litre to an outer corrugated fibreboard case 5.2 litre bottles may or may not be packed to an outer corrugated fibreboard case 6.2 litre bottles may or may not be packed to an outer corrugated fibreboard case 7 litre bottles may or may not be packed to an outer corrugated fibreboard case. 7.5 litre bottles, may or may not be, packed 2 x 7.5 litre to an outer corrugated fibreboard case

Type	Description
	10 litre jerrican, may or may not be, packed 2x10 litre to an outer corrugated fibreboard case 15 litre jerrican, may or may not be, packed 2x15 litre to an outer corrugated fibreboard case 20 litre jerrican may or may not be packed to an outer corrugated fibreboard case.
Opening:	28, 45, 50, 60 and 63 mm inner diameter
Closure:	28mm – from 0.05L up to 0.25L bottles 45mm – from 0.25L up to 2L bottles 50mm – from 0.25L up to 2L bottles 60mm – for 15L and 20L jerricans 63mm – for 3L, 5L, 5.2L, 6.2L, 7L, 7.5L, 10L, 15L and 20L bottles/jerricans
Seal:	Induction, compression or vented
Manner of construction	Co-extruded
UN/ADR	Compliant
Refillable or returnable	No

The packaging complies with ADR regulations, as it has been tested using the ADR test methods appropriate to the pack type, material and classification of the contents. An appropriate UN certificate has been issued.

Prothioconazole in GF-3307 is chemically and physically stable in COEX (HDPE/PA), F-HDPE and steel through two years of warehouse ambient storage. Fenpicoxamid showed loss  $> 5\%$  and  $\leq 10\%$  in COEX (HDPE/PA), F-HDPE and steel, through two years of warehouse ambient storage. Breakdown products (X12393285, X12335723, and X12314005) were quantitated and acceptable mass balance was demonstrated. The total mass balance of fenpicoxamid and its breakdown products was  $\geq 98.6\%$  in COEX (HDPE/PA), F-HDPE and steel through two years of warehouse ambient storage. All performance test properties were within specifications. The results demonstrate that GF-3307 chemical and physical stability is acceptable in COEX (HDPE/PA), F-HDPE and steel through two years of warehouse ambient storage. (Study FOR-14.37, Hofer, C.)

#### 4.2 Recommended methods and precautions (KCP 4.2)

Please refer to the safety data sheet for GF-3307 (KCP 4/01).  
Efficacy of tank cleaning is summarized under KCP 2.11 (LES 10126, Topham, D.)

#### 4.3 Emergency measures in the case of an accident (KCP 4.3)

Please refer to the safety data sheet for GF-3307 (KCP 4/01).

#### 4.4 Procedures for destruction or decontamination of the ppp and its packaging (KCP 4.5)

Please refer to the safety data sheet for GF-3307 (KCP 4/01).

## 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 2.1 2.3.1 2.4.2 2.5.1 2.6.1	Moe, T., Julien, T.	2016	Determination of Color, Physical State, Odor, Oxidizing and Reducing Action, Flammability, pH, Viscosity, and Density of GF-3307, an End Use Product Containing DE-777 and Prothioconazole FAPC-G-15-36 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
KCP 2.2.1 2.2.2 2.3.3 2.5.2	Dunning, J.	2016	Determination of Surface Tension, Explosive Properties, Auto-Ignition, Temperature (liquids and gases) and Oxidising Properties (liquids) of GF-3307 NAFST-15-159 Envigo CRS Ltd. GLP Not Published	N	Corteva Agriscience
KCP 2.4.1 2.7.1 2.7.4	Hofer, C.	2015	GF-3307 Two Week 54°C Accelerated Storage Stability and One Week 0°C Low Temperature Stability FOR-14-35 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
KCP 2.7.2	Hofer, C.	2015	GF-3307 Eight Week 40°C Accelerated Storage Stability in F-HDPE and COEX Bottles and Steel Drums FOR-14-36 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
KCP 2.7.5 2.8.2 2.8.6.1 2.8.6.2 2.8.6.3	Hofer, C.	2017	Two Year Ambient Storage Stability of GF-3307 in COEX and F-HDPE Bottles and Steel Drums FOR-14-37 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
4.4					
KCP 2.8.6.2	Stoltz, V.	2018	GF-3307 and GF-3308 Two Week 54°C Accelerated Storage Stability and One Week 0°C Low Temperature Stability: Emulsion Stability DAS Report No.: FOR-180883 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
KCP 2.7.5	Stoltz, G.	2018	30 Month Ambient Storage Stability of GF-3307 in COEX and F-HDPE Bottles and Steel Drums FOR-171251 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
KCP 2.11 4.2	Topham, D.	2016	Dow AgroSciences Clean Out Report for Fungicides: GF-2925, GF-3307, GF-3308, GF-3309, GF-3312 - Low Temperature Stability: Emulsion Stability DAS Report No.: LES 10126 Amega Sciences Non GLP Not Published	N	Corteva Agriscience

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

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
CA 2.1/1 CA 2.3/1	Moe TE	2012a	Determination of Color, Physical State, Odor, Melting Point and Decomposition Temperature of XDE-777 Pure Active Ingredient DAS Report No.: FAPC-G-12-29 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
CA 2.2/1	Comb AL	2012a	Determination of Vapour Pressure of XDE-777	N	Corteva



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			DAS Report No.: NAFST-12-114 Huntingdon Life Sciences Ltd. GLP Not Published		Agriscience
CA 2.2/2	Frank A	2013	Calculation of the Henrys Law Constants for XDE-777 from Unbuffered and pH 5, 7, and 9 Buffered Water DATA GUIDELINE European Regulation (EC) No 11072009, OECD Point 2.3.2 DAS Report No.: NAFST-12-227 Dow AgroSciences LLC Non GLP Not Published	N	Corteva Agriscience
CA 2.3/2	Moe TE	2012b	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Explodability, pH and Bulk Density of XDE-777 Technical Grade Active Ingredient DAS Report No.: FAPC-G-12-30 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
CA 2.3/3	Moe TE	2012c	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Explodability, pH and Bulk Density of XDE-777 Technical Grade Active Ingredient DAS Report No.: FAPC-G-12-31 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
CA 2.4/1	Elliott T	2014	X772777: Determination of Spectral Characteristics (UVVisible Absorption and Molar Absorptivities, Mass Spectrum, Infrared Spectrum, and NMR) (Revision) DAS Report No.: NAFST-12-223 ABC Laboratories, Inc. GLP Not Published	N	Corteva Agriscience
CA 2.5/1	Comb AL	2012b	Determination of Water Solubility for XDE-777 DAS Report No.: NAFST-12-110 Huntingdon Life Sciences Ltd. GLP Not Published	N	Corteva Agriscience

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
CA 2.6/1	Comb AL	2012c	Determination of Organic Solvent Solubility for XDE-777 TGAI DAS Report No.: NAFST-11-352 Huntingdon Life Sciences Ltd. GLP Not Published	N	Corteva Agriscience
CA 2.6/2	Comb AL	2012d	Determination of Organic Solvent Solubility for XDE-777 TGAI DAS Report No.: NAFST-12-137 Huntingdon Life Sciences Ltd. GLP Not Published	N	Corteva Agriscience
CA 2.7/1	Comb AL	2012e	Determination of Octanol/Water Partition Coefficient for XDE-777 by Shake Flask Method DAS Report No.: NAFST-12-111 Huntingdon Life Sciences Ltd. GLP Not Published	N	Corteva Agriscience
CA 2.8/1	Comb AL	2012f	Determination of Dissociation Constant of XDE-777 DAS Report No.: NAFST-12-112 Huntingdon Life Sciences Ltd. GLP Not Published	N	Corteva Agriscience
CA 2.9/1 CA 2.11/1 CA 2.12/1 CA 2.13/1	Comb AL	2012g	Determination of Surface Tension, Flammability (solids), Explosive Properties, Relative Self-Ignition Temperature for Solids and Oxidising Properties for XDE-777 TGAI DAS Report No.: NAFST-11-351 Huntingdon Life Sciences Ltd. GLP Not Published	N	Corteva Agriscience
CA 2.9/2 CA 2.11/2 CA 2.12/2 CA 2.13/2	Comb AL	2012h	Determination of Surface Tension, Flammability (solids), Explosive Properties, Relative Self-Ignition Temperature for Solids and Oxidising Properties for XDE-777 TGAI DAS Report No.: NAFST-12-136 Huntingdon Life Sciences Ltd. GLP Not Published	N	Corteva Agriscience
CA 2.14/1	Comb AL	2012i	Determination of Relative Density of XDE-777	N	Corteva

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			DAS Report No.: NAFST-12-113 Huntingdon Life Sciences Ltd. GLP Not Published		Agriscience
CA 2.14/2	Xiong Q Lewer P Graupner PG Frank A Pearson DL	2013	Determination of the Absolute Configuration of XDE-777 Using Vibrational Circular Dichroism (VCO) DAS Report No.: DAI 1277 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
CP 2.1/1 CP 2.3/1 CP 2.4/1 CP 2.5/1 CP 2.6/1	Moe TE	2012	Determination of Color, Odor, Physical State, Oxidizing and Reducing Action, Flashpoint, Explodability, pH, Viscosity, and Density of GF-2925, an End Use Product Containing XDE-777 DAS Report No.: FAPC-G-12-52 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
CP 2.2/1 CP 2.3/2 CP 2.5/2	Comb AL	2012	Determination of Surface Tension, Explosive Properties, Auto-Ignition Temperature (liquids and gases) and Oxidizing Properties (liquids) of GF-2925 DAS Report No.: NAFST-12-228 Huntingdon Life Sciences Ltd. GLP Not Published	N	Corteva Agriscience
CP 2.7/1	Hofer C	2012a	GF-2925 Two Week 54°C Accelerated Storage Stability and One Week 0°C in Glass DAS Report No.: FOR-12-12 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
CP 2.7/2 CP 2.7.2/1 CP 2.7.3/1 CP 2.7.4.1/1 CP 2.7.7/1	Hofer C	2012b	GF-2925 Accelerated Storage Stability; Eight Week 40°C in PET and HDPE DAS Report No.: FOR-12-13 Dow AgroSciences LLC GLP Not Published	N	Corteva Agriscience
CP 2.7/3	Hofer C	2014	Three Year Ambient Storage Stability of GF-2925 in PET and HDPE; Two Year Ambient Interim Report DAS Report No.: FOR-12-14	N	Corteva Agriscience

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
			Dow AgroSciences LLC GLP Not Published		

**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
-	-	-	-	-	-