

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-4021

Product name: LaDiva

Chemical active substances:

Halauxifen-methyl 10 g a.s./L (9.594 g a.e./L)

Picloram 48 g a.s./L

Aminopyralid 32 g a.s./L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new submission of the product)

Applicant: Corteva AgriScience

Submission date: December 2020

MS Finalisation date: December 2021 (initial Core Assessment)

January 2023 (final Core Assessment)

Version history

When	What
November 2020	New submission of GF-4021 to the Central Zone.
December 2021	Initial assessment by the zRMS 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 .
January 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. Information no longer relevant is struck through and shaded .

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

Noticed data gaps are:

- The two years storage stability study is ongoing.

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

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Telephone	+33 (0)1 30 23 13 36
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Telephone
Contact

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

1.2.1 Producers of the preparation

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

1.2.2 Producers of the active substances

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

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

1.2.3.1 Active substance 1

Endpoint	Aminopyralid
Reference	COMMISSION IMPLEMENTING REGULATION (EU) No 891/2014 of 14 August 2014
Purity of active substance	920 g/kg minimum

No impurities of toxicological or ecotoxicological concern in aminopyralid.

1.2.3.2 Active substance 2

Endpoint	Halauxifen-methyl
Reference	Commission Implementing Regulation (EU) 2015/1165
Purity of active substance	930 g/kg minimum

No impurities of toxicological or ecotoxicological concern in aminopyralid.

1.2.3.3 Active substance 3

Endpoint	Picloram
Reference	COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011
Purity of active substance	920 g/kg minimum

Relevant impurity Hexachlorobenzene (HCB) max. 0.05 g/kg

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

Trade name: LaDiva

Company code number: GF-4021

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)

Table 1-1: 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 or g/kg)	Technical content*** (%w/w)
Aminopyralid	32 g/L	28.8 – 35.2 g/L	34.8 g/L	3.7
Halauxifen-methyl	10 g/L	8.5 – 11.5 g/L	10.8 g/L	1.1
Picloram	48 g/L	43.2 – 52.8 g/L	52.2 g/L	5.5

* FAO limits up to 25 g/L \pm 15%; above 25 g/L up to 100 g/L \pm 10%

** Based on the minimum purity of 920 g/kg for aminopyralid, 930 g/kg for halauxifen-methyl and 920 g/kg for picloram

*** Based on the density of the formulation = 0.9457 g/mL (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1-2: Safener and synergists

There are no safeners or synergists in GF-4021.

Table 1-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Hexachlorobenzene	0.05 g/kg

1.4.2 Information on the active substances (KCP 1.4.2)

Table 1-4: Information on Aminopyralid

Type	Name/Code Number
ISO common name	Aminopyralid
CAS No.	150114-71-9
EC No.	604-721-7
CIPAC No.	771

Table 1.4-5: Information on Halauxifen-methyl

Type	Name/Code Number
ISO common name	Halauxifen-methyl
CAS No.	943831-98-9
EC No.	695-056-1
CIPAC No.	970.201

Table 1.4-6: Information on Picloram

Type	Name/Code Number
ISO common name	Picloram

Type	Name/Code Number
CAS No.	1918-02-1
EC No.	217-636-1
CIPAC No.	174

Table 1.4.3: Information on safeners/ synergists / co-formulant

CONFIDENTIAL information is provided separately (Part C).

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

Type: Emulsifiable Concentrate

[Code: EC]

1.6 Function (KCP 1.6)

Herbicide.

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 brown liquid at 21.2°C. It is not explosive, has no oxidising properties. The product has a flash point of >100 °C. It has a self-ignition temperature of 239 °C. In aqueous solution, it has a pH value around 3.49 at 18.8 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The two years storage stability study is ongoing. The packaging claimed in the section 4 (COEX and PET) are acceptable as a storage stability study at elevated temperature for 14 days was carried out in COEX and PET. Its technical characteristics are acceptable for an *EC* formulation.

The intended concentration of use is 0.083% to 0.25%.

No application is being made for the authorisation of the combined use of the preparation with any other product. However, the product is expected to be compatible (physically/chemically) in mixtures with other commercial products in agitated spray tanks.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only. Notifier Proposals for Risk and Safety Phrases (KCP 12):

Not classified based on physical and chemical properties.

Compliance with FAO specifications:

The product GF-4021 complies with FAO specifications.

Formulation used for test

Please refer to the Part C of the current formulation. The formulation GF-4021 used for the tests is the same formulation presented in Part C.

Table 2-2-1: 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	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	Brown, liquid at 21.2°C	Y	Terrill, M., 191969 (2020)	Accepted.
Explosive properties (KCP 2.2.1)	EC A14	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	Not explosive	Y	Comb, T., 191970 (2020)	Accepted.
Oxidizing properties (KCP 2.2.2)	EC A21	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	Not oxidising	Y	Comb, T., 191970 (2020)	Accepted.
Flash point (KCP 2.3.1)	EC A9	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	>100°C	Y	Terrill, M., 191969 (2020)	Accepted.
Flammability (KCP 2.3.2)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Self-heating (KCP 2.3.3)	EC A15	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	239°C	Y	Comb, T., 191970 (2020)	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC 191	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	Before Storage: 0.89% as H ₂ SO ₄ After 2 weeks storage at 54°C in PET: 0.92% as H ₂ SO ₄ After 2 weeks storage at 54°C in COEX: 0.93% as H ₂ SO ₄	Y	Wozniak, H., 191874 (2020)	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC 75.3	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	Before Storage: 3.49 at 18.8°C (~1% w/v dilution) After 2 weeks storage at 54°C in PET: 3.59 at 19.0°C (~1% w/v dilution) After 2 weeks storage at 54°C in COEX: 3.62 at 19.1°C (~1% w/v dilution) Metal Compatibility for GF-4021: Coupons of common metals were selected to understand corrosivness of GF-4021. For each coupon, 120 glass jar with 40 mL of GF-4021 was prepared. The coupons were	Y	Wozniak, H., 191874 (2020)	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																		
			<p>partially submerged in GF-4021, each jar was securely capped, and jars were measured before and after exposing them to GF-4021 to calculate corrosion rates in milli inch/year (mpy), mass changes (%) and volume swell (%).</p> <p>One mpy is equivalent to 0.001 inch/year (0.025 mm/year).</p> <p>Therefore, the following Corrosion Rates are equivalent:</p> <table><tr><th>Metal/Alloy</th><th>Corrosion Rate (mpy)</th><th>Corrosion Rate (mm/year)</th></tr><tr><td>Carbon Steel</td><td>13.47</td><td>0.342</td></tr><tr><td>Stainless Steel 304L</td><td>2.71</td><td>0.0688</td></tr><tr><td>Stainless Steel 316L</td><td>2.44</td><td>0.0620</td></tr><tr><td>Aluminum 5052</td><td>0.16</td><td>0.0041</td></tr><tr><td>Aluminum 6061</td><td>0.24</td><td>0.0061</td></tr></table> <p>The Corrosion Rates in mm/year are well below the allowable mm/year limits as specified in Table 2.16.1 of Part 2 to Annex I of Regulation (EC) No 1272/2008 (CLP) and Table 2.8.3.4 of the UN Transport of Dangerous Goods Model Regulations, and therefore will not trigger hazard classification for supply or transport.</p>	Metal/Alloy	Corrosion Rate (mpy)	Corrosion Rate (mm/year)	Carbon Steel	13.47	0.342	Stainless Steel 304L	2.71	0.0688	Stainless Steel 316L	2.44	0.0620	Aluminum 5052	0.16	0.0041	Aluminum 6061	0.24	0.0061	N	Wolok, R., (2021)	Accepted. Since the Corrosion Rates in mm/year are well below the allowable limit, this product does not trigger hazardous classification.
Metal/Alloy	Corrosion Rate (mpy)	Corrosion Rate (mm/year)																						
Carbon Steel	13.47	0.342																						
Stainless Steel 304L	2.71	0.0688																						
Stainless Steel 316L	2.44	0.0620																						
Aluminum 5052	0.16	0.0041																						
Aluminum 6061	0.24	0.0061																						
Viscosity (KCP 2.5.1)	OECD 114	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	28.8 mPa's at 20°C 13.7 mPa's at 40°C	Y	Terrill, M., 191969 (2020)	Accepted.																		
Surface tension (KCP 2.5.2)	EC A5 OECD 115	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	29.0 mN/m at 0.083% v/v dilution 27.5 mN/m at 0.25% v/v dilution 23.5 mN/m for neat test item	Y	Comb, T., 191970 (2020)	Accepted.																		
Relative Density (KCP 2.6.1)	OECD 109	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	0.9457 g/mL	Y	Terrill, M., 191969 (2020)	Accepted.																		
Bulk density (KCP 2.6.2)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-																		
Storage Stability after 14 days at 54° C	AM-191129 For a full validation details	TSN401447 3.3wt% aminopyralid, 1.08wt%	Before Storage: 3.3% w/w aminopyralid, 5.1% w/w picloram, 1.07% w/w	Y	Wozniak, H., 191874 (2020)	The product showed no significant physical changes																		

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.7.1)	please refer to the dRR Part B Section 5.	halauxifen-methyl, 5.1wt% picloram	<p>halauxifen-methyl</p> <p><u>After 2 weeks of storage at 54°C in COEX/PA:</u> 3.3% w/w aminopyralid, 5.1% w/w picloram, 1.06% w/w halauxifen-methyl</p> <p><u>After 2 weeks of storage at 54°C in PET:</u> 3.3% w/w aminopyralid, 5.1% w/w picloram, 1.07% w/w halauxifen-methyl</p>			<p>after accelerated storage and all performance properties were within acceptable limits.</p> <p>No toxicologically, ecotoxicologically or environmentally relevant impurities are formed upon storage, evaluation of this parameter after storage is not necessary.</p> <p>The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in COEX or PET.</p>
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	N/A	N/A	Formulation was stable at 2wk 54°C, no need for an alternate temperature to be monitored	N/A	N/A	-
Minimum content after heat stability testing (KCP 2.7.3)	N/A	N/A	Refer to annex 2.7.1	N/A	N/A	-
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC 39.3	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	The stored product showed no significant physical changes after 0°C storage for one week in glass. It can be concluded that GF-4021 is stable after one week of 0°C storage in glass.	Y	Wozniak, H., 191874 (2020)	Accepted.
Ambient temperature shelf life (KCP 2.7.5)	N/A	N/A	Ambient temperature study currently ongoing, will be provided upon completion.	N/A	N/A	The final Ambient temperature study is currently ongoing, and should be provided upon completion.
Shelf life in months (if less than 2 years) (KCP 2.7.6)	N/A	N/A	Not relevant. GF-4021 is stable for at least two years in PET and COEX.	N/A	N/A	Ambient temperature study is currently ongoing, and should be provided upon completion.
Wettability (KCP 2.8.1)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Persistence of foaming (KCP 2.8.2)	CIPAC 47.3	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	Results were <60 mL foam after 1 minute at 0.25% v/v GF-4021 before and after two weeks of 54°C storage in PET and COEX in standard water D.	Y	Wozniak, H., 191874 (2020)	Accepted.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Suspensibility (KCP 2.8.3.1)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Spontaneity of dispersion (KCP 2.8.3.2)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Dispersion stability (KCP 2.8.3.3)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Degree of dissolution and dilution stability (KCP 2.8.4)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Wet sieve test (KCP 2.8.5.1.2)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Dust content (KCP 2.8.5.2.1)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Particle size of dust (KCP 2.8.5.2.2)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Attrition (KCP 2.8.5.3)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Hardness and integrity (KCP 2.8.5.4)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Emulsifiability (KCP 2.8.6.1)	CIPAC 36.3	TSN401447 3.3wt% aminopyralid, 1.08wt% halauxifen-methyl, 5.1wt% picloram	Results were <2 mL of cream on top and no oil after 2 hours at 0.083% v/v and 0.25% v/v GF-4021 in standard water A and D before and after two weeks of 54°C storage in PET and COEX. Testing was concluded after 2-hour observations.	Y	Wozniak, H., 191874 (2020)	Accepted.
Emulsion stability (KCP 2.8.6.2)			See KCP 2.8.6.1			-
Re-emulsifiability (KCP 2.8.6.3)			See KCP 2.8.6.1			-
Flowability (KCP 2.8.7.1)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Pourability (KCP 2.8.7.2)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dustability following accelerated storage (KCP 2.8.7.3)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	The product is expected to be physically compatible in mixtures with other commercial products in agitated spray tanks.	-	-	No application is being made for the authorisation of the combined use of the preparation with any other product.
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	The product is expected to be chemically compatible in mixtures with other commercial products in agitated spray tanks.	-	-	No application is being made for the authorisation of the combined use of the preparation with any other product.
Adhesion to seeds (KCP 2.10.1)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Distribution to seed (KCP 2.10.2)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-
Other/special studies (KCP 2.11)	N/A	N/A	Not applicable for an EC formulation.	N/A	N/A	-

Table 2-1.6-2: Physical and Chemical Properties before and after Storage for 2 weeks at 54°C of GF-4021.

Test Description	Method	Initial Results	Results after 2 weeks at 54°C in COEX/PA	Results after 2 weeks at 54°C in PET
Active Substance Content: Halauxifen-methyl Aminopyralid Picloram HCB (relev. imp.)	AM-191129	1.07% 3.3% 5.1% -	1.06% 3.3% 5.1% -	1.07% 3.3% 5.1% -
Colour Physical State Appearance	Visual Visual Visual	Brown liquid with a mild odour.	Brown liquid with a mild odour.	Brown liquid with a mild odour.
pH Value	CIPAC MT 75.3	3.49 at 18.8°C on ~1% w/v preparation	3.62 at 19.1°C on ~1% w/v preparation	3.59 at 19.0°C on ~1% w/v preparation
Acidity/Alkalinity	CIPAC MT 191	0.89% as H ₂ SO ₄	0.93% as H ₂ SO ₄	0.92% as H ₂ SO ₄
Persistent Foaming 0.1 % w/v mL 1 min 12 min	CIPAC MT 47.3	≤ 60 mL foam after 1 minute at 0.25% w/v 2 1.5	≤ 60 mL foam after 1 minute at 0.25% w/v 40 32	≤ 60 mL foam after 1 minute at 0.25% w/v 44 38
Emulsion Stability & Re-Emulsification	CIPAC MT 36.3	Results were <2 mL of cream on top and no oil after 2 hours at 0.083% v/v and 0.25% v/v GF-4021 in standard water A and D before and after two weeks of 54°C storage.	Results were <2 mL of cream on top and no oil after 2 hours at 0.083% v/v and 0.25% v/v GF-4021 in standard water A and D before and after two weeks of 54°C storage in COEX.	Results were <2 mL of cream on top and no oil after 2 hours at 0.083% v/v and 0.25% v/v GF-4021 in standard water A and D before and after two weeks of 54°C storage in PET.
Low Temperature Stability	CIPAC MT 39.3	The stored product showed no significant physical changes after 0°C storage for one week in glass. Emulsion stability and re-emulsification (CIPAC MT 36.3) results were no cream and no oil at 0.083% v/v and 0.25% v/v GF-4021 in standard water A and D before and after one-week storage at 0°C. Testing was concluded at 2 hours. Based on the physical test results obtained from the study, it can be concluded that GF-4021 is stable after one week of 0°C storage in glass.		
Packaging Assessment	N/a	Test substance was added to two 1-L polyethylene terephthalate (PET) bottles (obtained from Ipackchem, DAS specification EU 158-02) with bore seal closures (obtained from Procap, DAS specification EU338-01), and two 1-L high density polyethylene/polyamide (COEX) bottles (obtained from Mullackal, Item description: 1000 ml Co-Ex bottle) with induction heat seal closures (obtained from Shenxin, China, DAS specification CHN300). The package types tested are the representation of the predicted commercial packaging material.	The 1-L COEX bottles showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product after two weeks of 54°C storage.	The 1-L PET bottles showed no indications of significant weight loss or physical deterioration that would interfere with the safe handling of the product after two weeks of 54°C storage.

Observations and Conclusion

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

Table 2-1.6-3: Physical and Chemical Properties before and after Storage for 2 Years at Ambient Temperature
Study ongoing and the data will be presented upon completion.

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)

Study Comments: KCP 4.1/01	Ambient temperature study is currently ongoing, will be provided upon completion. The accelerated stability data indicate a shelf life of at least 2 years at ambient temperature when stored in COEX/PA and PET.
Agreed endpoint: KCP 4.1/01	The packaging material COEX/PA and PET tested in the Accelerated storage stability study have been approved and are suitable for the storage of the plant protection product.

Table 4-1: Packaging information for PET

Type	Description
Material:	PET
Shape/size:	Bottles/Jerrican 0.05, 0.10, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10L, 15L and 20L 0.05 litre bottles may or may not be packed, 30 x 0.05 litre to an outer corrugated fibreboard case. 0.10 litre bottles may or may not be packed 30 x 0.10 litre to an outer corrugated fibreboard case. 0.15 litre bottles may or may not be packed 20 x 0.15 litre to an outer corrugated fibreboard case. 0.25 litre bottles may or may not be packed 12 x 0.25 litre or 24 x 0.25 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 10 litre jerrican, may or may not be packed 2x10litre 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.
Wall Thickness:	min 0.2 mm
Opening:	28 mm, 45 mm and 63 mm
Closure:	Screw cap 28mm – from 0.05L up to 0.15L bottles 45mm – from 0.25L up to 2L bottles 63mm – for 3L, 5L, 10L, 15L and 20L bottles/jerricans
Seal:	Induction, bore, compression or vented
Manner of construction	Stretch blow moulded
UN/ADR	compliant
Refillable or returnable	No

Table 4.1-2: Packaging information for Coex PE/PA

Type	Description
Material:	HDPE/PA
Shape/size:	0.1 litre bottles may or may not be packed 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. 10 litre jerrican, may or may not be, packed 2x10litre to an outer corrugated fibreboard case 15 litre jerrican, may or may not be packed 2x15litre to an outer corrugated fibreboard case

Type	Description
	20 litre jerrican may or may not be packed to an outer corrugated fibreboard case.
Wall Thickness:	min 0.2 mm
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, 10L, 15L and 20L bottles/jerricans
Seal:	Induction, compression or vented
Manner of construction	Co-extruded
Barrier Material:	PA
UN/ADR	compliant
Refillable or returnable	No

4.2 Procedures for Cleaning Application Equipment

4.2.1 Procedures for cleaning application equipment and protective clothing

Refer to the 4.2.2.

4.2.2 Effectiveness of the cleaning procedures

Study Comments: KCP 4.2/01	Acceptable.
Agreed endpoint: KCP 4.2/01	The proposed cleaning procedure is considered sufficient.

TANK Cleaning-washing procedure (GF-4021)

Rinsing

After the end of application, thoroughly rinse sprayers and flush hoses, boom, filters and nozzles with clean water to reduce risk of forming hardened deposits which might become difficult to remove.

Rinse all other associated application equipment. Diluted spray solution can be sprayed over the treated crop/field at high speed lower pressure without exceeding the registered rate. Drain the tank.

To avoid subsequent injury to crops other than cereals, all spraying equipment must be thoroughly cleaned both inside and out using cleaning agent spray cleaner as follows

Any contamination on the outside of the spray equipment should be removed by washing with clean water.

Cleaning

1. Rinse inside of tank with clean water and flush through booms and hoses, using at least one tenth of the spray tank volume. Drain tank completely.

2. For tank with rotating internal cleaning nozzle: Fill the tank with 10% of tank capacity of clean water. Add the recommended rate of cleaning agent. Agitate and flush boom and hoses with the cleaning solution for 15 minutes. Drain the tank completely.

For tank without an internal rotating cleaning nozzle: Half fill the tank with clean water and add cleaning agent at the recommended rate. Agitate and flush the boom and hoses with the cleaning solution. Complete tank filling with water and allow standing for 15 minute under agitation. Flush the booms and hoses and drain the tank completely.

3. Rinse the tank with clean water and flush through boom and hoses using at least one tenth of the spray tank volume. Drain tank completely.

4. Nozzles and filters should be removed and clean separately with cleaning agent solution containing cleaning agent by its recommend concentration.
5. For disposal of washing, follow code of practice for Using Plant Protection Products. Do not spray onto to sensitive crop or land intended for cropping with sensitive crops

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 KCP 2.3.1 KCP 2.5.1 KCP 2.6.1	Terrill, M.	2020	Determination of Color, Physical State, Odor, Oxidizing and Reducing Action, Flammability, pH, Viscosity, and Density of GF-4021, an End Use Product Containing Aminopyralid, Halauxifen-methyl, and Picloram. DAS Report No.: 191969. Crop Protection Product Design and Process R&D. GLP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)
KCP 2.2.1 KCP 2.2.2 KCP 2.3.3 KCP 2.5.2	Comb, T.	2020	Determination of Surface Tension, Explosive Properties, Auto-Ignition Temperature and Oxidising Properties of GF-4021. DAS Report No.: 191970 AgroChemex Environmental LTD GLP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)
KCP 2.4.1 KCP 2.4.2/01 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.6.1	Wozniak, H.	2020	GF-4021 Two Week 54°C Accelerated Storage Stability in PET and COEX and One Week 0°C Low Temperature Stability. DAS Report No.: 191874 Crop Protection Product Design and Process R&D. GLP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)
KCP 2.7.2			Ambient Storage Stability Study of GF-4021 (Study ongoing and will be provided upon completion). DAS Report No.: 191875 GLP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)
KCP 2.4.2/02	Wolok, R.	2021	Metal Compatibility for GF-4021. Metal Compatibility Letter, October 5, 2021 GLP (Y/N): N Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)

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

Not necessary.

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

Not necessary to characterize the product.